

ISSUE

Whether Part C of Title XVIII of the Social Security Act (“Act”) or the Medicare Advantage Plan provides coverage for the tumor treating fields therapy utilizing an electric stimulation device requested by . . .

FINDINGS OF FACT

1. enrolled in the Blue Cross Blue Shield of North Carolina, a Medicare Part C health plan. (Exh. 3, p. 8)
2. 1 female with a relevant medical history of recurrent glioblastoma multiforme. was diagnosed with unresectable anaplastic astrocytoma in May 2015. She underwent radiation therapy with concurrent Temodar from July 2, 2015, to August 14, 2015. (Exh. 3, p. 104)
3. On September 17, 2015, Dr. REDACTED prescribed for six months use of Optune. Optune is a tumor treating fields therapy comprised of an electric field generator and insulated transducer arrays. (Exh. 2, pp. 1–2)
4. On September 17, 2015, Novocure requested pre-approval from the Health Plan for coverage of tumor treating fields therapy utilizing the Optune device. (Exh. 3, p. 50)
5. On September 18, 2015, Dr. REDACTED wrote a letter supporting the medical necessity of this item for Dr. REDACTED stated that has failed systemic chemotherapy and all radiotherapy options approved for her clinical scenario. Dr. REDACTED further opined that is not a surgical candidate. She concluded that there are few if any available options that would benefit ; given her particular clinical scenario. (Exh. 2, pp. 4–5)
6. Novocure’s tumor treating fields therapy device is FDA approved for the treatment of glioblastoma. (Exh. 2, pp. 647–651)

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. 42 C.F.R. § 405.1014; Social Security Act (“the Act”) section 1869(b)(1)(A). The Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary unless later reviewed by the Medicare Appeals Council. *Id.*

To be timely, the request for hearing must be received by OMHA within sixty days after the Appellant receives the QIO reconsideration unless the time is extended for good cause as provided in §478.22. 42 C.F.R. § 478.42(b)(1). The Appellant is presumed to have received the QIO reconsideration five days after the date noted on the first page of the reconsideration unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3) and 42 C.F.R. § 478.42(b)(2).

To be entitled to a hearing before an ALJ, a party must meet the amount in controversy requirements. 42 C.F.R. § 405.1002(a)(2).

B. Scope of Review

The ALJ considers all issues not decided entirely in the Appellant's favor at any prior level of review. 42 C.F.R. § 405.1032. The ALJ may give notice to the parties if any other issue will be addressed at the hearing. *Id.* The ALJ may also decide a case on the record and not conduct a hearing if the appellant and all other parties indicate in writing they do not wish to appear at a hearing. 42 C.F.R. §§ 405.1000(g), 405.1032(a) and 405.1038. The ALJ may also decide a case on the record if the evidence in the hearing record supports a wholly favorable finding. *Id.*

A party may not offer new evidence for the first time at the ALJ level unless the ALJ finds good cause exists why the evidence was not submitted to a prior decision maker. This restriction on new evidence is not applicable to unrepresented beneficiaries or to oral testimony given during the course of a hearing. 42 C.F.R. §§ 405.966(c), 405.1018(c-d), 405.1028(a), and 405.1030(c).

C. Standard of Review

The ALJ reviews and evaluates the evidence without regard to the findings made by the lower levels on the claim (*de novo* review). 42 C.F.R. § 405.1000(d). The Appellant bears the burden of proving each element of the Medicare claim by a preponderance of the evidence. Sections 1814(a)(1), 1815(b), and 1833(e) of the Act; 42 C.F.R. §§ 424.5(a)(6), 405.1018, 405.1028, and 405.1030.

II. Principles of Law

A. Statutes and Regulations

The Medicare Program, Title XVII of the Act, is administered through CMS. The Secretary of the Department of Health and Human Services is authorized to enter into contracts with private entities for the day-to-day operations of the program. §1842(a)(1)(A) of the Act.

According to § 1862(a)(1)(A) of the Act, Medicare may not make a payment under Part A or Part B for anything which is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Section 1833(e) of the Act states that “[n]o payment shall be made to any provider of services or other person under this Part unless there has been furnished such information as may be

necessary in order to determine the amounts due such provider or other person under this part for the periods with respect to which the amounts are being paid or for any prior period.” 42 U.S.C. § 13951(e).

Section 1852 of the Act states that under Medicare Part C, a Medicare Advantage (“MA”) Organization offering an MA plan must provide enrollees with coverage of those items and services for which benefits are available under parts A and B. The Regulations support this basic requirement in 42 C.F.R. § 422.100(c), where it states, “An M+C plan includes at a minimum basic benefits, and also may include mandatory and optional supplemental benefits.” Part (c)(1) defines basic benefits as “all Medicare-covered services...” While covering basic benefits, Medicare Advantage Organizations must “provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B) and that are available to beneficiaries residing in the plan’s service area...”

While enrolled in an MA plan, an enrollee is entitled to and restricted by the limitations and conditions of that program with respect to Medicare coverage and reimbursement. In turn, the MA plan must make available to an enrollee, or provide reimbursement for, at least all services covered under Part A and Part B of Medicare. 42 CFR § 422.101.

The Regulations also describe the authorities with which MA Organizations must comply while providing basic Part A and Part B services. The Regulation at 42 C.F.R. § 422.101(b) requires MA Organizations to comply with:

1. CMS’s national coverage determinations;
2. General coverage guidelines included in original Medicare manuals and instructions unless superseded by operational policy letters or regulations in this part; and
3. Written coverage decisions of local carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered under the M+C organization.

B. Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than an National Coverage Determination, can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. *See also* 42 C.F.R. § 405.1060. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that establishes criteria for coverage of selected types of medical items and services in the form of manuals and local coverage determinations (“LCDs”).

Section 1869(f)(2) of the Act provides that Administrative Law Judges will give substantial deference to LCDs or CMS program guidance when applicable, and if they do not follow the policy they must explain why in their decision. *See also* 42 C.F.R. § 405.1062.

Applicable to the instant appeal is CGS Administrators, LLC, Local Coverage Determination (LCD) L34823: Tumor treating fields therapy (LCD L34823) (October 2015). LCD L34823 states that tumor treating fields therapy (E0766) will be denied as not reasonable and necessary.

LCD L34823.

C. Evidence of Coverage

Blue Cross Blue Shield of North Carolina is a Medicare Advantage Organization. The Health Plan's 2015 Evidence of Coverage states that members receive Medicare Part B coverage for everything that Original Medicare covers.

ANALYSIS

is requesting coverage from her Medicare Part C plan for tumor treating fields therapy. On behalf of , Novocure contends this item is medically reasonable and necessary because methods of treatment have failed and this treatment is safe and effective. The Independent Review Entity denied coverage because neither the Health Plan nor Medicare Part B offers coverage tumor treating fields therapy for any indication.

Medicare regulations require the Health Plan to pay for medical services, procedures and equipment if regular Medicare Part A or Part B would pay for the same services, procedures or equipment. Blue Cross Blue Shield of North Carolina's Evidence of Coverage states that members receive coverage for everything that original Medicare covers.

The Medicare Contractor CGS Administrators, LLC, created a Local Coverage Determination addressing the issue in this case. That LCD simply states that tumor treating fields therapy will be denied as not reasonable and necessary. There is no additional detail or guidance contained within the LCD. The only substance is a reference section entitled "Sources of Information and Basis for Decision." That section lists seventeen separate citations which presumably support the summary conclusion that tumor treating fields therapy is not reasonable and necessary. The list is noteworthy in that the most recent citation is from 2013.

Pursuant to section 1869(f)(2) of the Act, Administrative Law Judges are to give substantial deference to Local Coverage Determinations. If an ALJ does not follow an applicable LCD, an explanation must be given. The ALJ chooses to deviate from the LCD for the following reasons. Tumor treating fields therapy using an electric stimulation device is FDA approved. FDA approval necessarily means the treatment has been deemed safe and effective. The most recent phase three clinical trial¹, published in December 2015 shows that this treatment is effective because it significantly prolongs the disease progression of glioblastoma, and increases the overall odds of survival. The 2015 study is given greater weight than the LCD both because it is recent proof of efficacy and because the LCD lacks any substantive guidance. Finally, .. suffers from glioblastoma. Dr. REDACTED wrote a letter in support of tumor

¹ Stupp R., Taillibert S., Kanner A., et al. Maintenance Therapy With Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma: A Randomized Clinical Trial. *JAMA*. 2015; 314(23): 2535-2543. Doi:10.1001/jama.2015.16669. See <http://jama.jamanetwork.com/article.aspx?articleid=2475463>

treating fields therapy. She highlighted that [REDACTED] had failed systemic chemotherapy and all radiotherapy options approved for her clinical scenario. Dr. [REDACTED] further opined that [REDACTED] is not a surgical candidate. She concluded that there are few if any available options that would benefit [REDACTED], given her particular clinical scenario. Therefore the ALJ concludes that tumor treating fields therapy was medically reasonable and necessary in this case, and Medicare covers this service.

CONCLUSIONS OF LAW

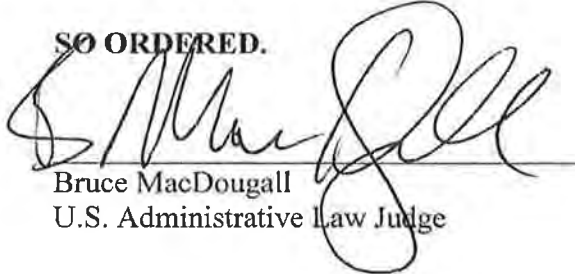
The decision is FULLY FAVORABLE. In accordance with the Health Plan's Evidence of Coverage and § 1862(a)(1)(A) of the Act, the Health Plan is required to provide coverage for the tumor treating fields therapy.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

Dated: APR 04 2016

SO ORDERED.



Bruce MacDougall
U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Cleveland, Ohio

Appeal of:	OMHA Appeal No.: 1-6062856997R1
Enrollee:	Medicare: Part C
HICN:	Before: David Mackintosh Administrative Law Judge
Coverage Requested: July 5, 2016	

DECISION

After carefully considering the evidence and arguments presented of record, a decision is entered which is **FULLY FAVORABLE** to Appellant/Beneficiary/Enrollee).

Procedural History

Appellant requested pre-approval for tumor treatment field therapy (TTFT) provided with the Optune antimitotic electrical field device¹ (E0766) from his Medicare Advantage Plan, Premara Blue Cross (the Plan), which is administered by Providence Health Plan (PHP). This request was denied through reconsideration by an Independent Review Entity (IRE) on January 16, 2017 (Exhibit 1, Pages 1 - 36). The Enrollee elected to proceed with the requested TTFT treatment without the requested authorization and continued TTFT through December 31, 2017 at which time his coverage with the Plan ended. By agreement of all parties, the dates of service under review are August 30, 2016 through December 31, 2017 (Dates of Service) (Hearing Audio).

On April 3, 2017, the Office of Medicare Hearings and Appeals ("OMHA") received an untimely request for a hearing before an Administrative Law Judge ("ALJ") filed by Tanya Lane from Novocure. Ms. Lane argued that Novocure had just found out (on March 30, 2017) that Maximus (the IRE) had upheld its denial (Exhibit 3, Pages 1-3). On April 11, 2017, the undersigned dismissed Novocure's untimely request for an ALJ hearing because though Novocure claimed to be the Enrollee's appointed representative, the record contained no appointment of representative form (Exhibit 4, Page 3). Novocure obtained a signed appointment of representative form from the Enrollee, dated April 25, 2017, and appealed the dismissal to the Medicare Appeals Council (Council) (Exhibit 5, Pages 1-7). On May 23, 2017, the Council vacated the undersigned's dismissal and remanded the case to the undersigned ALJ for further proceedings (Exhibit 5, Pages 256-258(A)). The amount in controversy satisfies the amount in controversy jurisdictional requirement (Exhibit 1, Page 35).

On August 22, 2018, an ALJ telephonic hearing was initiated from Cleveland, Ohio. Appellant was represented by the following Novocure staff: Julie Miles, RN (Clinical Appeals Specialist), Tanya Lane (Case Manager Team Leader), and Dan McCoy (Manager of Case Management), who knowingly waived Appellant's right to be represented by legal counsel. Joanne Tremblay, RN (Nurse Care Coordinator with PHP) appeared for the Plan. All testimony was provided under oath. Exhibits 1 through 8 were admitted into the record without objection. The attached Exhibit List is incorporated herein.

¹ The Optune device is referred to as an electrical stimulation device in the HCPC Code. The therapy it provides is referred to by the NCCN as alternating electric field therapy, but is also known as tumor treatment field therapy (TTFT).

Issues

Whether the Plan is required to cover the TTFT (E0766) provided to the Enrollee during the Dates of Service, under Medicare Part C?

Findings of Fact

After careful consideration of the entire record, a preponderance of the evidence establishes the following facts:

1. In 2011, the Food and Drug Administration (FDA) conducted premarket approval (PMA) review and determined the Optune device is indicated for the treatment of recurrent glioblastoma multiforme (GBM) following histologically or radiologically confirmed recurrence in the supra-tentorial region of the brain after receiving chemotherapy (Exhibit 7, Pages 2-5).
2. A clinical trial studied the use of TTFT along with maintenance TMZ on 315 patients with glioblastoma who had completed standard chemo-radiation therapy. This study demonstrated significant and prolonged progression-free status and overall improved survival rates for TTFT with TMZ versus a control group using only TMZ. The study was ceased secondary to concerns it would be unethical to not provide tumor treatment fields to the control group (Citation: Stupp & Taillibert et al., "Maintenance Therapy With Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma." JAMA 314, no. 23 (2015), 2535. doi:10.1001/jama.2015.16669) (Exhibit 2, Pages 11-21; Exhibit 5, Pages 23-32; Hearing Audio).
3. In 2015, FDA PMA review found the Optune device is indicated as treatment for adult patients (22 years of age or older) with histologically-confirmed GBM when used in conjunction with TMZ; with newly diagnosed supratentorial GBM following maximal debulking surgery and completion of radiation therapy with concomitant standard of care chemotherapy (Exhibit 7, Pages 2-5).
4. In 2016 and 2017, TTFT plus adjuvant TMZ was a National Comprehensive Cancer Network (NCCN) Category 2A recommendation following postoperative standard brain radiation therapy with concurrent TMZ for new onset GBM². For recurrent GBM, the NCCN Clinical Practice Guidelines recommend reirradiation or TTFT as a Category 2B recommendation. NCCN Clinical Practice Guidelines in Oncology recommend TTFT for combatting glioblastoma (Exhibit 2, Pages 8-10; Exhibit 5, Pages 18-21).
5. The 69 year-old male Beneficiary's medical history includes hypertension, hyperlipidemia, seizures, and a transient ischemic attack (Exhibit 2, Pages 29-55; Exhibit 5, Pages 41 & 47).
6. On May 5, 2016, the Beneficiary sought treatment at a hospital emergency room (E/R) with sudden left-sided weakness, slurred speech, nausea, and headache. A CT of the head revealed a 5.1 x 5.6 cm intraparenchymal hematoma in the right cerebral hemisphere. Further diagnostic testing found a large

² On 2/23/18, the NCCN upgraded this recommendation to a category 1 recommendation (Source: NCCN Guidelines for Central Nervous System Cancers V.1.2018 –Follow-Up on 02/23/18 @ <https://www.nccn.org/>). While this new guideline was not applicable to the Dates of Service, it shows a growing medical consensus throughout the Dates of Service.

intracranial hemorrhage involving the right parietal lobe with associated vasogenic edema and mass effect. A MRI was done and found a 4.7 cm x 4.5 cm x 4.2 cm right parietal mass. The Beneficiary's condition declined and a craniotomy was performed with evacuation of hemorrhage and tumor resection. Pathology confirmed grade IV GBM (Exhibit 2, Pages 29-55; Exhibit 5, Pages 41-42).

7. The evolving treatment plan for the Enrollee's newly diagnosed grade IV GBM included radiation treatment (6,000 cGy delivered in 30 fractions completed on July 16, 2016) with concurrent Temodar (temozolomide) (TMZ), and tumor treatment field therapy (TTFT) (prescribed by Dr. Stephen H. Thatcher on June 10, 2016) with TTFT treatment beginning August 29, 2016 (Exhibit 2, Pages 29-55; Exhibit 2, Page 42).
8. The Beneficiary elected to proceed with the requested TTFT treatment without the Plan's prior authorization. He used the device through January 2018. The Beneficiary experienced scalp irritation from the Optune electrodes and was prescribed clobetasol for use on the irritated skin areas. The Beneficiary lived 17 months after beginning TTFT treatment, a period beyond the life expectancy for maintenance therapy with TMZ alone (Exhibit 2, Pages 29-55; Exhibit 5, Pages 41-107 & Hearing Audio).
9. The Beneficiary was enrolled with the Plan throughout the Dates of Service (Exhibit 1, Pages 25-32; Hearing Audio).

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner (Social Security Act (Act) § 1869(b)(1)(A)).

In implementing this statutory directive, the Secretary delegated authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. See 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Council. While NCDs are binding upon ALJs, LCDs and CMS Program Guidance is not, though ALJs must give substantial deference to these policies and, if they do not follow the policy, must explain why in their decision (Section 1869(f) of the Act, 42 C.F.R. §§405.1060-2),

An ALJ hearing is only available if the remaining amount in controversy is \$160 or more for requests filed in calendar year 2017. See 81 Fed. Reg. 65651 (Sep. 23, 2016). The request for hearing is timely if filed within sixty days after receipt of the reconsideration determination (20 C.F.R. § 404.933(b)(1)).

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in the appellant's favor; however, if evidence presented

before or during the hearing causes the ALJ to question a fully favorable decision, the appellant will be notified and it will be considered an issue at hearing (42 C.F.R. § 405.1032(a)).

Unless the ALJ dismisses the hearing, the ALJ will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. The decision must be based on evidence offered at the hearing or otherwise admitted into the record (42 C.F.R. § 405.1046(a)).

C. Standard of Review

The ALJ conducts a de novo review of each claim at issue and issues a decision based on the hearing record (42 C.F.R. § 405.1000(d) and Section 557 of the Administrative Procedure Act). De novo review requires the ALJ to review and evaluate evidence without regard to the findings of prior determinations on the claim and make an independent assessment relying upon the evidence and controlling laws.

II. Principles of Law

A. Statutes, Regulations, Policies

The Medicare Program, Title XVII of the Act (42 U.S.C. §§1395-139ggg) is administered through CMS. The Secretary of the Department of Health and Human Services is authorized to enter into contracts with private entities for the day-to-day operations of the program, §1842(a)(1)(A) of the Act.

The MA program (Part C of the Act) provides that a MA organization offering a MA plan must provide enrollees, at a minimum, with all basic Medicare-covered services by furnishing the benefits directly or through arrangements, or by paying for the benefits. Basic benefits are benefits defined as “all Medicare covered services, except hospice services.” Mandatory supplemental benefits are defined as “services not covered by Medicare that an MA enrollee must purchase as part of an MA plan that are paid for in full, directly by (or on behalf of) Medicare enrollees, in the form of premiums or cost sharing. Optional supplemental benefits are defined as “health services not covered by Medicare that are purchased at the option of the MA enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost sharing. These services may be grouped or offered individually.” (§1852(a) of the Act, 42 CFR §422.100).

MA organization health plans must provide coverage for all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B). Further, MA’s must comply with national coverage determinations as promulgated by the Centers for Medicare and Medicaid Services. 42 CFR §422.101. MA organizations must disclose to each beneficiary enrolling in a MA plan offered by the organization a detailed content of plan description, including, but not limited to, the plan’s service area, benefits, access, out-of-area coverage, emergency coverage, premiums and cost sharing (such as co-payments, deductibles and coinsurance). This information must be offered at the time of enrollment and at least annually after that, in a clear, accurate and standardized form. 42 CFR 422.111. MA organizations may specify the networks of providers from whom enrollees may obtain services as long as the MA organization ensures that all covered services, including additional or supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan with reasonable promptness and in a manner which assures continuity in the provision of benefits (§1852 (d) of the Act; 42 U.S.C § 1395w-22(d); 42 CFR §422.112).

Notwithstanding any other provision of Title XVIII of the Act, Section 1862(a) of the Act [42 U.S.C. § 1395y(a)(1)(A)] limits the payments that may be made under Part A or Part B, stating in pertinent part that, “no payment may be made under Part A or Part B for any expenses incurred for items or services — (1)(A) which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to

improve the functioning of a malformed body member . . .” (*Also see* 42 CFR § 411.15(k)(1)). Additionally, § 1833(e) of the Act [42 U.S.C. § 1395l(e)] prohibits Medicare payment for any claim that lacks such information as may be necessary in order to determine the amounts due such provider.

B. Policy and Guidance

Section 1871(a)(2) of the Act states that no rule, requirement, or statement of policy can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program unless it is promulgated as a regulation by CMS, with the only exception being national coverage determinations (NCDs). See 42 CFR § 405.1060. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance describing the criteria for coverage of selected items and services in the form of manuals and local coverage determinations (LCDs), respectively.

The DME MAC’s LCD for Tumor Treatment Field Therapy (TTFT) (LCD L34823, revised 01/01/2017) indicates TTFT (E0766) will be denied as not reasonable and necessary (L34823 for services performed on or after 01/01/2017). An earlier version of LCD L34823 denied TTFT in 2016.

C. The Plan’s Evidence of Coverage

The Plan’s 2017 Evidence of Coverage (EOC) excludes from coverage services considered not reasonable and necessary, according to the standards of Original Medicare; as well as experimental medical and surgical procedures, equipment, and medications (Exhibit 8, Page 1, EOC Ch. 4, Section 3.1, Page 99).

Analysis

The Plan denied Appellant’s pre-approval request for TTFT (E0766) finding the Optune device is considered new technology and investigational with only preliminary evidence of clinical efficacy. The IRE denied the Optune TTFT device because this treatment has been deemed not reasonable and necessary. Appellant argues that the Optune device was approved by the FDA for the treatment of newly diagnosed glioblastoma in combination with temozolomide after standard resection and radiation therapy. Appellant indicates the survivability of patients using Optune technology (with TMZ) increases to 20.9 months versus 16 months for patients treated with TMZ alone (Exhibit 1, Pages 3-5 & 25-29; Exhibit 6, Pages 6-10; Hearing Audio).

An MA plan must cover for enrollees all items and services covered by Medicare Part A (except hospice services) and Part B that are available to beneficiaries in the plan’s service area. An MA plan may also offer supplemental health care benefits (§ 1852(a) of the Act & 42 C.F.R. §§ 422.100(c)(1), 422.101(a)).

Applicable Medicare Part B local coverage policy indicates TTFT (E0766) will be denied as not reasonable and necessary (L34823). The undersigned declines to follow this policy as it fails to offer any reasoning or support for its brightline rule which wholly ignores recent applicable medical literature and NCCN guidelines³. Revised LCDs should help a Provider understand the basis of why a claim is paid or denied (Section §1869(f)(2) of the Act & 42 C.F.R. §405.1062; *Also see development guidelines – MPIM Ch. 13, Section 13.1.3*).^{4,5}

³ A fact acknowledged by the DME MAC in a letter to Novocure, dated August 7, 2018, by which the DME MAC commits to review LCD L34823 with respect newly diagnosed GBM in light of the latest research (to include the study completed and published in 2015) (Exhibit 8, Pages 1(A) – 3, *attached*). The undersigned takes judicial notices of this correspondence.

⁴ The DME MAC updated the Local Coverage Determination by stripping all references to applicable research in the treatment of GBM. In fact, the updated LCD does not reference any research at all (LCD L34823).

Appellant suffered from stroke-like symptoms and presented to the E/R. He underwent resection and pathology confirmed a grade IV glioblastoma (GBM) diagnosis affecting his right parietal lobe. The Beneficiary underwent resection and was provided radiation with TMZ. Thereafter, Dr. Thatcher's plan for maintenance treatment of the newly diagnosed GBM included TTFT with concurrent TMZ (FOF 1-4). Medical literature shows patients using TTFT and TMZ following resection/radiotherapy have better survival rates than those patients using TMZ alone, with significant and prolonged progression-free status and overall improved rates of survival. The FDA performed PMA review and found the Optune device indicated for treating recurrent GBM with concurrent TMZ; for newly diagnosed GBM confirmed by histopathology and following maximal debulking surgery and completion of radiation therapy with concomitant standard of care chemotherapy (FOF 2 & 5). Accordingly, the NCCN recommends TTFT⁶ with concurrent TMZ as an appropriate maintenance treatment for newly diagnosed glioblastomas (FOF 6-7). Following a review of the entire record, including clinical studies supporting the use of TTFT in conjunction with TMZ as maintenance therapy for newly diagnosed GBM and guidelines established by the NCCN recommending the same: the undersigned finds the TTFT provided to the Enrollee in conjunction with TMZ, was medically reasonable and necessary for the treatment of the Enrollee's GBM throughout the Dates of Service. The undersigned therefore finds the requested TTFT (E0766) would be covered under Medicare Part B.⁷ Accordingly, the Plan is required to cover the TTFT (E0766) under Medicare Part C (§1852(a) of the Act & 42 C.F.R. § 422.100).

Conclusions of Law

Under Medicare Part C, the Plan is required to cover the tumor treatment field therapy (E0766) provided to the Enrollee from August 30, 2016 through December 31, 2017⁸.

ORDER

The Medicare Contractor is DIRECTED to process the claim in accordance with this decision.

SO ORDERED.

Dated: 9-13-18



David Mackintosh
Administrative Law Judge

Attachment: CGS letter to Novocure, dated August 7, 2018.

⁵ A recent Council decision (M-17-6134) finds LCDs binding on MA Plan. The undersigned agrees but finds a Medicare Part C enrollee's right to ALJ review is not subject to restrictions placed upon an MA Plan (*see* FN4).

⁶ Brain tumors grow when their cells multiply in number. Electrical fields painlessly interrupt this process, slowing down the growth of tumors that cannot be removed by surgery alone. (Source: HopkinsMedicine.org (@ https://www.hopkinsmedicine.org/healthlibrary/test_procedures/neurological/Tumor-Treating_Field_for_Brain_Tumors_22.TTFieldsForBrainTumors)).

⁷ The undersigned finds that Medicare Beneficiaries with Part C coverage must be afforded the same rights as Medicare Part B beneficiaries pursuant to 42 CFR §422.101. Pursuant to Section §1869(f)(2) of the Social Security Act, ALJs have authority to decline to follow a LCD, so long as such departure is explained (See also 42 C.F.R. §405.1062). The rights of a Part C enrollee include the right to an ALJ appeal with all that this entails under Medicare Part B (42 CFR §422.602 & 42 CFR §422.101).

⁸ See Paragraph 1 of the Procedural History regarding the Dates of Services agreed to by all parties.



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Cleveland, Ohio

Appeal of:	OMHA Appeal No.: 1-7905328956
Beneficiary:	Medicare: Part B
HICN:	Before: David Mackintosh Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented of record, a decision is entered which is **FULLY FAVORABLE** to (Appellant/Beneficiary).

Procedural History

Appellant submitted a claim for tumor treatment field therapy (TTFT) provided with the Optune antimitotic electrical field device¹ (E0766) for the following rental dates: November 6, 2017; December 6, 2017; and January 6, 2018 (Dates of Service). Appellant's claim was denied through reconsideration by a Qualified Independent Contractor (QIC) on August 17, 2018 (Exhibit 1, Pages 1-7).

On September 26, 2018, the Office of Medicare Hearings and Appeals (OMHA) received Appellant's timely request for a hearing before an Administrative Law Judge (ALJ) filed by Appellant's representative, Debra Parrish, Esq. The amount in controversy satisfies the amount in controversy jurisdictional requirement (Exhibit 1, Page 16 and Exhibit 3, Pages 1-8). Additional medical records were received after the request for ALJ hearing was received. These documents were admitted into evidence as Exhibit 5 in this Beneficiary appeal (42 C.F.R. § 405.1018(d)(2)).

On October 31, 2018, an ALJ telephonic hearing was initiated from Cleveland, Ohio. Appellant appeared through Debra Parrish, Esq. (Appellant's Counsel) and Julie Miles, RN (Chief Appeals Specialist with Novocure (Supplier)). The relevant CMS Contractors were notified but did not respond. All testimony was provided under oath. Exhibits 1 through 5 were admitted into the record without objection. The attached Exhibit List is incorporated herein.

Issues

Whether the tumor treatment field therapy (E0766) which the Supplier provided to the Beneficiary during the Dates of Service is covered under Medicare Part B?

¹ The Optune device is referred to as an electrical stimulation device in the HCPC Code. The therapy it provides is referred to by the NCCN as alternating electric field therapy, but is also known as tumor treatment field therapy (TTFT).

Findings of Fact

After careful consideration of the entire record, a preponderance of the evidence establishes the following facts:

1. In 2011, the Food and Drug Administration (FDA) conducted premarket approval (PMA) review and found the Optune device is indicated for the treatment of recurrent glioblastoma multiforme (GBM)² following histologically or radiologically confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The FDA classified the Optune device as durable medical equipment (DME)³ (Exhibit 2, Pages 74-78).
2. The Centers for Medicare & Medicaid Services (CMS) issued a letter dated July 26, 2013, indicating that the Optune device falls within the durable medical equipment category (Exhibit 2, Page 73).
3. A clinical trial studied TTFT with maintenance TMZ on 315 patients with GBM who had completed standard chemo-radiation therapy. The study demonstrated significant and prolonged progression-free status and overall improved survival rates for TTFT with Temozolomide (TMZ) versus a control of only TMZ. The study was ceased secondary to concerns it would be unethical to not provide tumor treatment fields to the control group (Citation: Stupp & Taillibert et al., "Maintenance Therapy With Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma." *JAMA* 314, no. 23 (2015), 2535. doi:10.1001/jama.2015.16669 (Exhibit 2, Pages 36-46)).
4. The 55 year-old male Beneficiary was in his usual state of health on November 14, 2014, when he noticed his left lower quadrant visual field was cut while viewing a computer monitor. A brain MRI which revealed a left occipital lobe mass lesion. Dr. Fredric Meyer of the Mayo Clinic performed the resection and the pathology found GBM, WHO grade IV, MGMT gene methylation (methylation score of 228.37). The Beneficiary was then provided radiation with concurrent Temodar (temozolomide or TMZ) (Exhibit 2, Page 24).
5. In 2015, FDA PMA review found the Optune device is indicated as treatment for adult patients (22 years of age or older) with histologically-confirmed GBM when used in conjunction with TMZ; with newly diagnosed supratentorial GBM following maximal debulking surgery and completion of radiation therapy with concomitant standard of care chemotherapy (Source: FDA.gov website @ https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034S013b.pdf).
6. In 2016 and 2017, TTFT plus adjuvant TMZ was a National Comprehensive Cancer Network (NCCN) Category 2A recommendation following postoperative standard brain radiation therapy with concurrent TMZ for new onset GBM. For recurrent GBM, the NCCN Clinical Practice Guidelines

² GBM is an aggressive cancer that can occur in the brain or spinal cord. GBM tumors form from astrocytes that support nerve cells. GBM can occur at any age but occur more often in older adults and can cause worsening headaches, nausea, vomiting and seizures. GBM is very difficult to treat and a cure is often not possible. Treatments may slow progression of the cancer and reduce signs/symptoms (Source: Mayo Clinic at <https://www.mayoclinic.org/diseases-conditions/glioblastoma/cdc-20350148>).

³ DME is equipment which: Can withstand repeated use; is primarily and customarily used to serve a medical purpose; generally is not useful to a person in the absence of an illness or injury; and is appropriate for use in the home. All requirements of the definition must be met before an item can be considered to be durable medical equipment MBPM, Ch. 5, § 110.1). The applicable PA indicates that TTFT devices are covered under the DME benefit (A52711) and the record includes a letter from CMS indicating the devices fall within the DME benefit category (FOF 2). There is no doubt the prescribed Optune antimitotic electrical field device (E0766) is DME and the record supports it is medically reasonable and necessary DME.

recommend reirradiation or TTFT as a Category 2B recommendation⁴. NCCN Clinical Practice Guidelines in Oncology recommend TTFT for combatting glioblastoma (Exhibit 2, Pages 33-35).

7. On March 6, 2017, the Supplier provided an Optune TTFT device (E0766) to the Beneficiary and instructed him on its use (Exhibit 2, Pages 7-23).
8. The evolving treatment plan developed by _____, MD included TMZ alone followed by the addition of valacyclovir on January 30, 2015, and cannabinoid oil. TTFT was added to his treatment regimen on July 13, 2017 (Exhibit 1, Page 24; and Exhibit 2, Page 24-29).
9. Dr. _____ MD, authored a Letter of Medical Necessity dated July 25, 2017, indicating the desire to initiate TTFT for treating the Beneficiary's GBM and asking for coverage. Dr. _____ notes FDA approvals for the Optune device for those with newly diagnosed GBM following debulking surgery, and radiation with concurrent TMZ; and the Optune device is indicated in the treatment of recurrent GBM in the supra-tentorial region of the brain after receiving chemotherapy. Dr. _____ indicates that, at the time of his request, Optune and adjuvant TMZ following post-operative standard brain radiation therapy with concurrent TMZ was an NCCN Category 2A recommendation (Exhibit 1, Pages 4-6).
10. The Beneficiary was seen by Dr. _____ on November 27, 2017. Dr. _____ noted the Beneficiary had completed 35 cycles of TMZ. He was using the Optune TTFT device, but was having issues with skin breakdown that he was treating with a steroid cream alternating with tacrolimus ointment/cream. The Beneficiary decided to hold TMZ (last cycle completed October 2-6, 2017) (Exhibit 2, Pages 24-29).
11. An MRI brain scan performed on November 27, 2017, show the Beneficiary's GBM has remained stable while he has used the TTFT device with no progression of disease (Exhibit 2, Pages 30-31).
12. On August 7, 2018, CGS (the DME MAC), through a letter authored by Dr. _____, MD, MPH, FACP, acknowledging its Local Coverage Determination for TTFT (LCD L34823)⁵ does not address coverage of TTFT for Beneficiaries with newly diagnosed GBM (Exhibit 4, Pages 14-16; and Hearing Audio).
13. The Supplier's representative testified the Beneficiary's GBM was a newly diagnosed GBM with no progression per MRI (Hearing Audio).

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human

⁴ On 2/23/18, the NCCN upgraded this recommendation to a **category 1 recommendation** (Source: NCCN Guidelines for Central Nervous System Cancers V.1.2018 -Follow-Up on 02/23/18 @ <https://www.nccn.org/>, *emphasis added*). While this new guideline was not applicable to the Dates of Service, it shows a growing medical consensus during this period.

⁵ Revised LCDs should help a Provider understand the basis of why a claim is paid or denied (Section §1869(f)(2) of the Act & 42 C.F.R. §405.1062; *Also see development guidelines* MPIM Ch. 13, Section 13.1.3). Recent updates to this LCD stripped out all references to applicable research in the treatment of GBM. An action not in accord with relevant MPIM guidance.

Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner (Social Security Act (Act) § 1869(b)(1)(A)).

In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council (70 Fed. Reg. 36386, 36387 (June 23, 2005)).

An ALJ hearing is only available if the remaining amount in controversy is \$160 or more for requests filed in calendar year 2018. See 82 Fed. Reg. 45592 (Sep. 29, 2017). The request for hearing is timely if filed within sixty days after receipt of the reconsideration determination (20 C.F.R. § 404.933(b)(1)).

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in the appellant's favor; however, if evidence presented before or during the hearing causes the ALJ to question a fully favorable decision, the appellant will be notified and it will be considered an issue at hearing (42 C.F.R. § 405.1032(a)). Unless the ALJ dismisses the hearing, the ALJ will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. The decision must be based on evidence offered at the hearing or otherwise admitted into the record (42 C.F.R. § 405.1046(a)).

The burden of proving each element of a Medicare claim lies with the appellant by preponderance of the evidence (i.e. satisfied through the submission of sufficient evidence in accordance with Medicare rules). See Sections 1814(a)(1), 1815(b), and 1833(e) of the Act; 42 C.F.R. § 424.5(a)(6), 42 C.F.R. § 405.1018, 42 C.F.R. § 405.1028, and 42 C.F.R. § 405.1030. All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Social Security Act and applicable implementing regulations, are binding on ALJ's (42 C.F.R. § 405.1063).

An appellant may offer new evidence for the first time at the ALJ level of appeal only upon a showing of good cause why the evidence was not submitted to the QIC or a prior decision maker. The ALJ will determine whether good cause exists for the late submission of the new evidence and may only consider the evidence in making a decision if good cause is found. This late evidence restriction does not apply to unrepresented beneficiaries (42 C.F.R. § 405.1018, 42 C.F.R. § 405.1028 & 42 C.F.R. § 405.1030).

C. Standard of Review

The ALJ conducts a de novo review of each claim at issue and issues a decision based on the hearing record. De novo review requires the ALJ to review and evaluate the evidence without regard to the findings of prior determinations on the claim and make an independent assessment relying upon the evidence and controlling laws (42 C.F.R. § 405.1000(d) & § 557 of the Administrative Procedure Act).

II. Principles of Law

A. Statutes and Regulations

Medicare Part B provides coverage to eligible beneficiaries for all or part of the cost of "medical and other health services," a term which is defined by the Act to include durable medical equipment (§§ 1831-1832 & 1861 of the Act).

Section 1833(e) of the Act states that “[n]o payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.”

Section 1862(a) of the Act states: “Notwithstanding any other provision of this title, no payment may be made under Part A or Part B for any expenses incurred for items or Services – (1)(A) which, . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . .” (42 U.S.C. §1395y(a)(1)(A); 42 C.F.R. §411.15(k)(1)).

Section 1879(a) of the Act and 42 C.F.R. §411.400(a)(2) provide that if the services provided are deemed to be not reasonable and necessary for the diagnosis and treatment of an illness or injury or to improve the functioning of a malformed body member, or are custodial in nature, payment under Part A may still be made if both the beneficiary and the provider of the services did not know, nor could reasonably have been expected to know, that the services would not be covered (*See also* 42 C.F.R. § 411.406).

42 C.F.R. § 414.200, et seq., establishes the payment provisions for durable medical equipment and prosthetic and orthotic devices.

B. Policy

An ALJ is bound by Medicare National Coverage Determinations (NCD). Although not bound by manuals, program memoranda and other issuances created by CMS and the carriers and intermediaries, an ALJ must accord substantial deference to them as valid interpretive rules that clarify the application of statutory and regulatory requirements. If an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed (42 C.F.R. § 405.1060-1062). The authority to promulgate manuals and other policy issuances is found, in part, in Section 1842 of the Act.

A Local Coverage Determination as established by § 522 of the Benefits Improvement and Protection Act, is a decision by a fiscal intermediary or carrier whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with §1862(a)(1)(A) of the Act (i.e., a determination as to whether the service is reasonable and necessary). A Local Coverage Determination for Tumor Treatment Field Therapy (TTFT) issued by the DME MAC (LCD L34823) indicates TTFT (E0766) will be denied as not reasonable and necessary (L34823 for services performed on or after 01/01/2017). However, recent CGS correspondence indicates this LCD does not pertain to newly diagnosed GBM (*see* Exhibit 4, Page 19).

C. Liability Provisions

Section 1879(a) of the Act provides that if the services provided are deemed to be not reasonable and necessary for the diagnosis and treatment of an illness or injury or to improve the functioning of a malformed body member or are deemed to be custodial, payment under Part B may still be made if the beneficiary assigned the claim and both the beneficiary and the provider of the services did not know, nor could reasonably have been expected to know, that the services would not be covered. Further, pursuant to § 1879(b) of the Act, if no payment may be made under this section, the beneficiary’s liability for the charges incurred may be waived if the beneficiary did not know, nor could be reasonably expected to know, that the services would not be covered.

Analysis

The QIC denied coverage finding there was insufficient documentation to quantify the effects of the device for the Beneficiary. Appellant argues the Beneficiary suffers from newly diagnosed with GBM which was first treated with surgery, chemotherapy, and radiation; and that the FDA has approved TTFT devices for treatment of GBM, finding the treatment to be safe and effective. Appellant's counsel asserts the Beneficiary's survival beyond the normal life expectancy for a GBM patient shows that TTFT has been an effective treatment (Exhibit 1, Pages 1-7; Exhibit 3, Pages 1-8; Hearing Audio).

LCD L34823 indicates TTFT (E0766) will be denied as not reasonable and necessary. However, the DME MAC recently acknowledged this policy does not address cases of newly diagnosed GBM (FOF 12). Accordantly, the undersigned declines to apply LCD L34823 because the MAC has found it to be inapplicable to this type of case (42 C.F.R. § 405.1062(b)).

The 55 year-old Beneficiary was diagnosed with GBM MGMT gene methylation. Following resection surgery, Appellant was provided radiotherapy and TMZ (FOF 4). On March 6, 2017, the Supplier provided the Beneficiary with an Optune device and provided instruction on its use (FOF 7). In the months that followed, TTFT was added to the Beneficiary's treatment regimen in addition to TMZ (FOF 8). The Beneficiary completed 35 cycles of TMZ (FOF 10). Medical literature shows patients using TTFT and TMZ following resection/radiotherapy have better survival rates than those patients using TMZ alone, with significant and prolonged progression-free status and overall improved rates of survival (FOF 3). The FDA's PMA review found the Optune device is indicated for treating newly diagnosed GBM, confirmed by histopathology, following maximal debulking surgery and completion of radiation therapy with concomitant standard of care chemotherapy (FOF 1 & 5). In this case, Appellant's resected GBM has remained stable while receiving TTFT (FOF 11). NCCN guidelines recommend using a TTFT device concurrently with TMZ as an appropriate therapy for treatment of GBM (FOF 6). Based upon the favorable clinical study presented in submitted medical literature and guidelines established by the NCCN; as well as Appellant's stable status using the TTFT device; the undersigned finds the supplied TTFT device, was medically reasonable and necessary for the treatment of the Beneficiary's GBM. Accordingly, the undersigned finds the Supplier's provision of the TTFT device (E0766) is covered under Medicare Part B during the Dates of Service (§1831, §1832 & §1861 of the Act).

Conclusions of Law

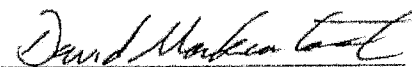
The provided tumor treatment field therapy (E0766)⁶ is covered under Medicare Part B for the rental dates of November 6, 2017; December 6, 2017; and January 6, 2018.

ORDER

The Medicare Contractor is DIRECTED to process the claim in accordance with this decision.

Dated: 11-5-18

SO ORDERED.



David Mackintosh
Administrative Law Judge

⁶ There is no charge data for TIFT devices (E0776) in CMS's 2017 and 2018 DME fee schedules (Source: CMS.gov at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule.html>). CGS can provide a gap-fill DME schedule for the Optune TTFT device (E0776) using the fee schedule amounts for comparable equipment, using properly calculated fee schedule amounts from a neighboring DME MAC or Part BMAC area, or using supplier price lists with prices in effect during the fee schedule data base year (MCPM, Ch. 23, §60.3).



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Cleveland, Ohio

Appeal of:	OMHA Appeal No.: 1-7737325030
Beneficiary:	Medicare: B
HICN:	Before: David Mackintosh Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented of record, a decision is entered which is **FULLY FAVORABLE** to (Appellant/Beneficiary).

Procedural History

Appellant requested coverage for tumor treatment field therapy (TTFT) provided with the Optune antimitotic electrical field device¹ (E0766) for rental dates July 13, 2017; August 13, 2017; September 13, 2017; and October 13, 2017. Appellant's claim was denied through reconsideration review by a Qualified Independent Contractor (QIC) on June 18, 2018 (Exhibit 1, Pages 1-7).

On August 2, 2018, the Office of Medicare Hearings and Appeals ("OMHA") received Appellant's timely request for a hearing before an Administrative Law Judge ("ALJ") filed by his representative Attorney Debra Parrish. The amount in controversy satisfies the amount in controversy jurisdictional requirement (Exhibit 1, Page 30 and Exhibit 3, Pages 1-5).

On September 11, 2018, an ALJ telephonic hearing was initiated from Cleveland, Ohio. Appellant was represented by Debra Parrish, Esq. (Counsel to Beneficiary). Novocure (Supplier) participated through its representative, Justin Kelly, RN, BSN (Regional VP Health Policy). Dan McCoy, Julie Miles, and Timothy Parks (all employees of the Supplier) observed. The relevant CMS Contractors were notified but did not respond. All testimony was provided under oath. Exhibits 1 through 5 were admitted into the record without objection. The attached Exhibit List is incorporated herein.

Issues

Whether the tumor treatment field therapy (E0766) which the Supplier provided to the Beneficiary during the Dates of Service is covered under Medicare Part B?

¹ The Optune device is referred to as an electrical stimulation device in the HCPC Code. The therapy it provides is referred to by the NCCN as alternating electric field therapy, but is also known as tumor treatment field therapy (TTFT).

Findings of Fact

After careful consideration of the entire record, a preponderance of the evidence establishes the following facts:

1. In 2011, Food and Drug Administration (FDA) conducted premarket approval (PMA) review and found the Optune device is indicated for the treatment of recurrent glioblastoma multiforme (GBM)² following histologically or radiologically confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The FDA classified the Optune device as durable medical equipment (DME) (Exhibit 7, Pages 97-152).
2. A clinical trial studied the use of TTFT along with maintenance TMZ on 315 patients with GBM who had completed standard chemo-radiation therapy. The study demonstrated significant and prolonged progression-free status and overall improved survival rates for TTFT with Temozolomide (TMZ) versus a control of only TMZ. The study was ceased secondary to concerns it would be unethical to not provide tumor treatment fields to the control group (Citation: Stupp & Taillibert et al., "Maintenance Therapy With Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma," JAMA 314, no. 23 (2015), 2535. doi:10.1001/jama.2015.16669 (Exhibit 2, Pages 60-69; Hearing Audio).
3. In 2015, FDA PMA review found the Optune device is indicated as treatment for adult patients (22 years of age or older) with histologically-confirmed GBM when used in conjunction with TMZ; with newly diagnosed supratentorial GBM following maximal debulking surgery and completion of radiation therapy with concomitant standard of care chemotherapy (Source: FDA.gov website (@ https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034S013b.pdf).
4. In 2016 and 2017, TTFT plus adjuvant TMZ was a National Comprehensive Cancer Network (NCCN) Category 2A recommendation following postoperative standard brain radiation therapy with concurrent TMZ for new onset GBM³. For recurrent GBM, the NCCN Clinical Practice Guidelines recommend reirradiation or TTFT as a Category 2B recommendation. NCCN Clinical Practice Guidelines in Oncology recommend TTFT for combatting glioblastoma (Exhibit 2, Pages 56-59).
5. The 63 year-old male Beneficiary's medical history includes acute gastric ulcer with perforation, Bell's palsy, chronic gastric ulcer, gastroesophageal reflux disease, hyperlipidemia, hypertension, seizure, diabetes mellitus type II, and glioblastoma multiforme (GBM) (Exhibit 2, Page 22).
6. In September 2016, the Beneficiary began experiencing acute onset memory problems and then trouble focusing. Work-up first revealed central nervous system disease. However, an MRI found a large area of vasogenic edema of the left temporal lobe and 2 enhancing lesions with vasogenic edema. On September 28, 2016, the Beneficiary underwent surgery (left temporal craniotomy) with

² Glioblastoma (GBM) is an aggressive type of cancer that can occur in the brain or spinal cord. GBM tumors form from cells called astrocytes that support nerve cells. GBM can occur at any age but tends to occur more often in older adults and can cause worsening headaches, nausea, vomiting and seizures. GBM, also known as glioblastoma multiforme, can be very difficult to treat and a cure is often not possible. Treatments may slow progression of the cancer and reduce signs and symptoms (Source: Mayo Clinic at <https://www.mayoclinic.org/diseases-conditions/glioblastoma/cde-20350148>).

³ On 2/23/18, the NCCN upgraded this recommendation to a **category 1 recommendation** (Source: NCCN Guidelines for Central Nervous System Cancers V.1.2018 - Follow-Up on 02/23/18 (@ <https://www.nccn.org> , *emphasis added*). While this new guideline was not applicable to the Dates of Service, it shows a growing medical consensus during this period.

partial resection of the left temporal gyrus. He was diagnosed with GBM IDH-1 (R132) wildtype involving the left posterior temporal area and the left anterior temporal area (Exhibit 2, Pages 21-28).

7. The evolving treatment plan developed by Dr. _____ for the newly diagnosed GBM included radiotherapy and concurrent TMZ. TTFT was added on April 13, 2017. TMZ was discontinued after December 5, 2017 as it had induced thrombocytopenia/neutropenia (Exhibit 2, Page 16, 29 & 52).
8. On April 13, 2017, the Supplier provided an Optune TTFT device (E0766) to the Beneficiary and instructed him on its use (Exhibit 2, Pages 16-20).
9. MRI brain scans show the Beneficiary's GBM has remained stable while he has used the TTFT device (Exhibit 2, Pages 34 & 39; Hearing Audio).
10. The Beneficiary is a patient of Dr. _____ MD. Dr. _____ authored a letter dated October 25, 2017, asking for authorization of benefits coverage for the Optune TTFT device for use in treating the Beneficiary's GBM. Dr. _____ notes this device is FDA approved for treating adult patients (22 years old and older) with histologically-confirmed GBM. Dr. _____ indicates the device, when used in conjunction with TMZ, is indicated for the treatment of adult patients with newly diagnosed, supratentorial GBM following maximal debulking surgery and completion of radiation therapy with concomitant standard of care chemotherapy (Exhibit 1, Pages 26-27).
11. On August 7, 2018, CGS (the DME MAC), though a letter authored by Dr. _____ MD, MPH, FACP, acknowledging its Local Coverage Determination for TTFT (LCD L34823) does not address coverage of TTFT for Beneficiaries with newly diagnosed GBM (Exhibit 4, Pages 19-21; and Hearing Audio).

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner (Social Security Act (Act) § 1869(b)(1)(A)).

In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council (70 Fed. Reg. 36386, 36387 (June 23, 2005)).

An ALJ hearing is only available if the remaining amount in controversy is \$160 or more for requests filed in calendar year 2018. See 82 Fed. Reg. 45592 (Sep. 29, 2017). The request for hearing is timely if filed within sixty days after receipt of the reconsideration determination (20 C.F.R. § 404.933(b)(1)).

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in the appellant's favor; however, if evidence presented

before or during the hearing causes the ALJ to question a fully favorable decision, the appellant will be notified and it will be considered an issue at hearing (42 C.F.R. § 405.1032(a)).

The burden of proving each element of a Medicare claim lies with the appellant by preponderance of the evidence (i.e. satisfied through the submission of sufficient evidence in accordance with Medicare rules). See Sections 1814(a)(1), 1815(b), and 1833(c) of the Act; 42 C.F.R. § 424.5(a)(6), 42 C.F.R. § 405.1018, 42 C.F.R. § 405.1028, and 42 C.F.R. § 405.1030. All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Social Security Act and applicable implementing regulations, are binding on ALJ's (42 C.F.R. § 405.1063).

An appellant may offer new evidence for the first time at the ALJ level of appeal only upon a showing of good cause why the evidence was not submitted to the QIC or a prior decision maker. The ALJ will determine whether good cause exists for the late submission of the new evidence and may only consider the evidence in making a decision if good cause is found. This late evidence restriction does not apply to unrepresented beneficiaries (42 C.F.R. § 405.1018, 42 C.F.R. § 405.1028 & 42 C.F.R. § 405.1030).

Unless the ALJ dismisses the hearing, the ALJ will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. The decision must be based on evidence offered at the hearing or otherwise admitted into the record (42 C.F.R. § 405.1046(a)).

C. Standard of Review

The ALJ conducts a de novo review of each claim at issue and issues a decision based on the hearing record. De novo review requires the ALJ to review and evaluate the evidence without regard to the findings of prior determinations on the claim and make an independent assessment relying upon the evidence and controlling laws (42 C.F.R. § 405.1000(d) & § 557 of the Administrative Procedure Act).

II. Principles of Law

A. Statutes and Regulations

Medicare Part B provides coverage to eligible beneficiaries for all or part of the cost of "medical and other health services," a term which is defined by the Act to include durable medical equipment (§§ 1831-1832 & 1861 of the Act).

Section 1833(e) of the Act states that "[n]o payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period."

Section 1862(a) of the Act states, in pertinent part: "Notwithstanding any other provision of this title, no payment may be made under Part A or Part B for any expenses incurred for items or Services - (1)(A) which, . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . ." (42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.15(k)(1)).

Section 1879(a) of the Act and 42 C.F.R. § 411.400(a)(2) provide that if the services provided are deemed to be not reasonable and necessary for the diagnosis and treatment of an illness or injury or to improve the functioning of a malformed body member, or are custodial in nature, payment under Part A may still be made if both the beneficiary and the provider of the services did not know, nor could reasonably have been expected to know, that the services would not be covered (*See also* 42 C.F.R. § 411.406).

42 C.F.R. § 414.200, et seq., establishes the payment provisions for durable medical equipment and prosthetic and orthotic devices.

B. Policy

An ALJ is bound by Medicare National Coverage Determinations (NCD). Although not bound by manuals, program memoranda and other issuances created by CMS and the carriers and intermediaries, an ALJ must accord substantial deference to them as valid interpretive rules that clarify the application of statutory and regulatory requirements. If an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed (42 C.F.R. § 405.1060-1062). The authority to promulgate manuals and other policy issuances is found, in part, in Section 1842 of the Act.

A Local Coverage Determination as established by § 522 of the Benefits Improvement and Protection Act, is a decision by a fiscal intermediary or carrier whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with §1862(a)(1)(A) of the Act (i.e., a determination as to whether the service is reasonable and necessary).

A Local Coverage Determination for Tumor Treatment Field Therapy (TTFT) issued by the DME MAC (LCD L34823) indicates TTFT (E0766) will be denied as not reasonable and necessary (L34823 for services performed on or after 01/01/2017). However, recent CGS correspondence indicates this LCD does not pertain to newly diagnosed GBM (*see* Exhibit 4, Page 19).

C. Liability Provisions

Section 1879(a) of the Act provides that if the services provided are deemed to be not reasonable and necessary for the diagnosis and treatment of an illness or injury or to improve the functioning of a malformed body member or are deemed to be custodial, payment under Part B may still be made if the beneficiary assigned the claim and both the beneficiary and the provider of the services did not know, nor could reasonably have been expected to know, that the services would not be covered. Further, pursuant to § 1879(b) of the Act, if no payment may be made under this section, the beneficiary's liability for the charges incurred may be waived if the beneficiary did not know, nor could be reasonably expected to know, that the services would not be covered.

Analysis

The QIC denied coverage for the supplied TTFT noting LCD L34823 states "Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary." The QIC also found currently published studies in the medical literature do not clearly document the effectiveness of the TTFT device. Appellant argues the effectiveness of the TTFT device has been demonstrated in clinical trials, is FDA approved, and is a recommended therapy for GBM pursuant to NCCN guidelines. Appellant further notes that the Beneficiary's post-diagnosis survival of almost 2 years using the TTFT device is testament to TTFT's effectiveness as the median post-diagnosis survival period for GBM patients is 10 months (Exhibit 1, Pages 1-7; Exhibit 3, Pages 1-5; Hearing Audio).

Applicable Medicare Part B local coverage policy indicates TTFT (E0766) will be denied as not reasonable and necessary (LCD L34823)⁴. The DME MAC has recently acknowledged this policy does

⁴ Revised LCDs should help a Provider understand the basis of why a claim is paid or denied (Section §1869(f)(2) of the Act & 42 C.F.R. §405.1062; *Also see development guidelines* - MPIM Ch. 13, Section 13.1.3). Instead of following this applicable policy, recent updates to this LCD stripped out all references to applicable research in the treatment of GBM.

not address cases of newly diagnosed GBM (FOF 10). Based upon the MAC's representation, the ALJ finds LCD L34823 to be inapplicable to this case. For this reason, the undersigned declines to follow LCD L 34823 policy in this case (42 C.F.R. § 405.1062(b)).

The 63 year-old Beneficiary developed acute onset memory problems with trouble focusing. Diagnostic testing including an MRI revealed a large area of vasogenic edema of the left temporal lobe and two enhancing lesions with vasogenic edema. In September 2016, the Beneficiary was newly diagnosed with GBM IDH-1 (R132) wildtype. Following surgery (left temporal craniotomy), Appellant was provided radiotherapy and TMZ. On April 13, 2017, TTFT was added to impair GBM growth (FOF 5-8). Medical literature shows patients using TTFT and TMZ following resection/radiotherapy have better survival rates than those patients using TMZ alone, with significant and prolonged progression-free status and overall improved rates of survival (FOF 2). The FDA performed PMA review and found the Optune device indicated for treating recurrent GBM with concurrent TMZ; and newly diagnosed GBM confirmed by histopathology and following maximal debulking surgery and completion of radiation therapy with concomitant standard of care chemotherapy (FOF 3). In fact in the instant case, Appellant has remained stable per MRI imaging despite his 2016 diagnosis (FOF 9). NCCN guidelines recommend using a TTFT device concurrently with TMZ as an appropriate therapy during treatment of GBM (FOF 4). As aforementioned, LCD L34823 does not address cases of newly diagnosed GBM (FOF 10-11). Based upon the favorable clinical study presented in submitted medical literature and guidelines established by the NCCN; as well as Appellant's stable status using the TTFT device;⁵ the undersigned finds the supplied TTFT device, which was provided in conjunction with TMZ, was medically reasonable and necessary for the treatment of the Beneficiary's GBM. Accordingly, the undersigned finds the Supplier's provision of the TTFT device (E0766) is covered under Medicare Part B during the Dates of Service.

Conclusions of Law

The provided tumor treatment field therapy (E0766)⁶ is covered under Medicare Part B for the rental dates of July 13, 2017; August 13, 2017; September 13, 2017; and October 13, 2017.

ORDER

The Medicare Contractor is DIRECTED to process the claim in accordance with this decision.

Dated: 9-27-18

SO ORDERED.



David Mackintosh

Administrative Law Judge

⁵ DME is equipment which: Can withstand repeated use; is primarily and customarily used to serve a medical purpose; generally is not useful to a person in the absence of an illness or injury; and is appropriate for use in the home. All requirements of the definition must be met before an item can be considered to be durable medical equipment MBPM, Ch. 5, § 110.1). The applicable PA indicates that TTFT devices are covered under the DME benefit (A52711) and the record includes a letter from CMS indicating the devices fall within the DME benefit category (FOF 2). There is no doubt the prescribed Optune antimitotic electrical field device (E0766) is DME and the record supports it is medically reasonable and necessary DME.

⁶ There is no charge data for TTFT devices (E0776) in the 2017 and 2018 DME fee schedules published by CMS (Source: CMS.gov at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DM-EPOS-FeeSchedule.html>). CGS can provide a gap-fill DME schedule for the Optune TTFT device (E0776) using the fee schedule amounts for comparable equipment, using properly calculated fee schedule amounts from a neighboring DME MAC or Part BMAC area, or using supplier price lists with prices in effect during the fee schedule data base year (MCPM, Ch. 23, §60.3).



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Cleveland, Ohio

Appeal of:	Novocure, Inc.	ALJ Appeal No.:	1-6459444850
Enrollee:	[REDACTED]	Medicare:	Part C
HICN:	xxx-xx-4179A	Before:	David Mackintosh Administrative Law Judge
Coverage Requested:	April 19, 2017		

DECISION

After carefully considering the evidence and arguments presented of record, a decision is entered which is **FULLY FAVORABLE** to Novocure, Inc. (Provider).

Procedural History

[REDACTED] (Enrollee) requested pre-approval for tumor treatment field therapy (TTFT) provided with the Optune antimitotic electrical field device¹ (E0766) from his Medicare Advantage Plan. Medical Mutual's MedMutual Advantage Classic HMO Plan (the Plan). This request was denied through reconsideration by an Independent Review Entity (IRE) on June 5, 2017 (Exhibit 1, Pages 1-5).

On June 30, 2017, the Office of Medicare Hearings and Appeals ("OMHA") received Appellant's timely request² for a hearing before an Administrative Law Judge ("ALJ"). The amount in controversy satisfies the amount in controversy jurisdictional requirement (Exhibit 3, Pages 1-2).

On August 22, 2017, an ALJ telephonic hearing was initiated from Cleveland, Ohio. Appellant appeared through Dan McCoy (Health Policy Analyst), who offered sworn testimony after first knowingly waiving Appellant's right to be represented by legal counsel. The Plan was noticed of the hearing, but did not respond and was not available when called. Exhibits 1 through 4 were admitted into the record without objection. The attached Exhibit List is incorporated herein.

Issues

Whether the Plan is required to approve the tumor treatment field therapy (E0766) for which the Enrollee has requested coverage.

¹ The Optune device is referred to as an electrical stimulation device in the HCPC Code. The therapy it provides is referred to by the NCCN as alternating electric field therapy, but is also known as tumor treatment field therapy (TTFT).

² Documentation submitted to the Plan lists Novocure, Inc. as the provider, rather than OSU Physician Group (Exhibit 1, Page 25). Additionally, the ALJ Hearing Request was submitted by Novocure, Inc. (Exhibit 3).

Findings of Fact

After careful consideration of the entire record, a preponderance of the evidence establishes the following facts:

1. The 66 year-old male Enrollee's medical history includes thyroid cancer, cognitive impairment, right homonymous hemianopsia, expressive dysphasia, right visual field defect, short-term memory problems, visual agnosia, craniotomy with resection, degenerative disc disease, hepatitis A, hypertension, hyperlipidemia, radiation therapy, hypothyroidism, malignant neoplasm of the cheek, metabolic syndrome, multiple congenital cysts of kidney, prostate cancer, osteoarthritis, osteoarthritis, hemorrhoid, and acute infarct in the left occipital lobe medial to the resection cavity (March 2017) (Exhibit 2, Pages 1, 4-5, 7-8, 12, 16, & 32).
2. In February 2017, the Enrollee sought treatment at a hospital emergency room (E/R) after noticing difficulty concentrating (he spent 3 hours completing paperwork instead of the 10 minutes it usually took him to complete). A CT/MRI found a left parietal mass with midline shift and mass effect. A subsequent biopsy found the Enrollee suffered from grade IV glioblastoma (also described as left parietal MGMT unmethylated glioblastoma) (Exhibit 2, Pages 1, & 8).
3. The evolving treatment plan for the Enrollee's grade IV glioblastoma included radiation, concurrent temozolomide (TMZ), and for tumor treatment field therapy (TTFT) (prescribed by Dr. Javier Gonzalez on April 19, 2017). Judith A. Lima, CNP noted the Enrollee was ineligible for clinical trials secondary to his history of cancer. (Exhibit 2, Pages 1 & 23).
4. TTFT plus adjuvant TMZ is a National Comprehensive Cancer Network (NCCN) Category 2A recommendation following postoperative standard brain radiation therapy with concurrent TMZ. NCCN Clinical Practice Guidelines in Oncology recommend TTFT for combatting glioblastoma (Exhibit 1, Pages 9; and Exhibit 2, Pages 48-51).
5. A recent clinical trial studied the use of TTFT along with maintenance TMZ on 315 patients with glioblastoma who had completed standard chemo-radiation therapy. This study demonstrated significant and prolonged progression-free status and overall improved survival rates for TTFT with TMZ versus a control group using only TMZ. The study was ceased secondary to concerns it would be unethical to not provide tumor treatment fields to the control group (Citation: Stupp & Taillibert et al., "Maintenance Therapy With Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma." JAMA 314, no. 23 (2015), 2535. doi:10.1001/jama.2015.16669 (Exhibit 2, Pages 119-128; Hearing Audio).
6. The Enrollee is a member of Medical Mutual's MedMutual Advantage Classic HMO Plan (Exhibit 1, Pages 19-302).
7. Prior to the date of the ALJ Hearing, the Enrollee elected to proceed with the requested treatment without prior authorization from the Plan (Hearing Audio).

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner (Social Security Act (Act) § 1869(b)(1)(A)).

In implementing this statutory directive, the Secretary delegated authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. See 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Council. While NCDs are binding upon ALJs, LCDs and CMS Program Guidance is not, though ALJs must give substantial deference to these policies and, if they do not follow the policy, must explain why in their decision (Section 1869(l) of the Act, 42 C.F.R. §§405.1060-2).

An ALJ hearing is only available if the remaining amount in controversy is \$160 or more for requests filed in calendar year 2017. See 81 Fed. Reg. 65651 (Sep. 23, 2016). The request for hearing is timely if filed within sixty days after receipt of the reconsideration determination (20 C.F.R. § 404.933(b)(1)).

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in the appellant's favor; however, if evidence presented before or during the hearing causes the ALJ to question a fully favorable decision, the appellant will be notified and it will be considered an issue at hearing (42 C.F.R. § 405.1032(a)).

Unless the ALJ dismisses the hearing, the ALJ will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. The decision must be based on evidence offered at the hearing or otherwise admitted into the record (42 C.F.R. § 405.1046(a)).

C. Standard of Review

The ALJ conducts a de novo review of each claim at issue and issues a decision based on the hearing record (42 C.F.R. § 405.1000(d) and Section 557 of the Administrative Procedure Act). De novo review requires the ALJ to review and evaluate evidence without regard to the findings of prior determinations on the claim and make an independent assessment relying upon the evidence and controlling laws.

II. Principles of Law

A. Statutes, Regulations, Policies

The Medicare Program, Title XVII of the Act (42 U.S.C. §§1395-139ggg) is administered through CMS. The Secretary of the Department of Health and Human Services is authorized to enter into contracts with private entities for the day-to-day operations of the program, §1842(a)(1)(A) of the Act.

The MA program (Part C of the Act) provides that a MA organization offering a MA plan must provide enrollees, at a minimum, with all basic Medicare-covered services by furnishing the benefits directly or through arrangements, or by paying for the benefits. Basic benefits are benefits defined as "all Medicare

covered services, except hospice services.” Mandatory supplemental benefits are defined as “services not covered by Medicare that an MA enrollee must purchase as part of an MA plan that are paid for in full, directly by (or on behalf of) Medicare enrollees, in the form of premiums or cost sharing. Optional supplemental benefits are defined as “health services not covered by Medicare that are purchased at the option of the MA enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost sharing. These services may be grouped or offered individually.” (§1852(a) of the Act, 42 CFR §422.100).

MA organization health plans must provide coverage for all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B). Further, MA’s must comply with national coverage determinations as promulgated by the Centers for Medicare and Medicaid Services. 42 CFR §422.101. MA organizations must disclose to each beneficiary enrolling in a MA plan offered by the organization a detailed content of plan description, including, but not limited to, the plan’s service area, benefits, access, out-of-area coverage, emergency coverage, premiums and cost sharing (such as co-payments, deductibles and coinsurance). This information must be offered at the time of enrollment and at least annually after that, in a clear, accurate and standardized form. 42 CFR 422.111. MA organizations may specify the networks of providers from whom enrollees may obtain services as long as the MA organization ensures that all covered services, including additional or supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan with reasonable promptness and in a manner which assures continuity in the provision of benefits (§1852 (d) of the Act; 42 U.S.C § 1395w-22(d); 42 CFR §422.112).

Notwithstanding any other provision of Title XVIII of the Act, Section 1862(a) of the Act [42 U.S.C. § 1395j(a)(1)(A)] limits the payments that may be made under Part A or Part B, stating in pertinent part that, “no payment may be made under Part A or Part B for any expenses incurred for items or services — (1)(A) which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . .” (Also see 42 CFR § 411.15(k)(1)). Additionally, § 1833(e) of the Act [42 U.S.C. § 1395l(e)] prohibits Medicare payment for any claim that lacks such information as may be necessary in order to determine the amounts due such provider.

B. Policy and Guidance

Section 1871(a)(2) of the Act states that no rule, requirement, or statement of policy can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program unless it is promulgated as a regulation by CMS, with the only exception being national coverage determinations (NCDs). See 42 CFR § 405.1060. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance describing the criteria for coverage of selected items and services in the form of manuals and local coverage determinations (LCDs), respectively.

A Local Coverage Determination for Tumor Treatment Field Therapy (TTFT) issued by the DME MAC (LCD L34823) indicates TTFT (E0766) will be denied as not reasonable and necessary (L34823 effective 10/01/2015 – Present). This LCD provides no sources of information for this policy and no basis for its decision (“Sources of Information and Basis of Decision: N/A”) (LCD L34823).

C. The Plan’s Evidence of Coverage

The Plan’s 2017 Evidence of Coverage (EOC) excludes from coverage services considered not reasonable and necessary, according to the standards of Original Medicare; as well as experimental medical and surgical procedures, equipment, and medications (EOC Ch. 4, Section 3.1).

Analysis

The Plan and IRE denied Appellant's pre-approval request for TTFT (E0766) finding this treatment is not reasonable and necessary for the treatment of brain tumors and is non-covered by Medicare pursuant to LCD L34823. Appellant argues that TTFT plus adjuvant TMZ is an NCCN Category 2A recommendation³ following postoperative standard brain radiation therapy with concurrent temozolomide. Appellant relates that TTFT in combination with temozolomide is the most appropriate option for the Enrollee (Exhibit 1, Pages 1-5, 9, & 19-21; Hearing Audio).

An MA plan must cover for enrollees all items and services covered by Medicare Part A (except hospice services) and Part B that are available to beneficiaries in the plan's service area. An MA plan may also offer supplemental health care benefits (§ 1852(a) of the Act & 42 C.F.R. §§ 422.100(c)(1), 422.101(a)).

Applicable Medicare Part B local coverage policy indicates TTFT (E0766) will be denied as not reasonable and necessary (L34823). The undersigned declines to follow this policy as it fails to offer any reasoning or support for its brightline rule which wholly ignores applicable medical literature and NCCN guidelines, which are supportive of the requested coverage (Section §1869(f)(2) of the Act & 42 C.F.R. §405.1062; *Also see development guidelines* – MPIM Ch. 13, Section 13.1.3).

The Enrollee suffers from grade IV glioblastoma. His physician's plan of treatment includes TTFT with concurrent TMZ (FOF 1-3). Medical literature shows patients using TTFT and TMZ following resection/radiotherapy have better survival rates than those patients using TMZ alone, with significant and prolonged progression-free status and overall improved rates of survival. Accordingly, the NCCN recommends TTFT with concurrent TMZ as an appropriate therapy during treatment of glioblastomas (FOF 4-5). Based upon the favorable clinical study presented in submitted medical literature and guidelines established by the NCCN, the undersigned finds the requested TTFT, which is to be provided in conjunction with TMZ, was medically reasonable and necessary for the treatment of the Enrollee's glioblastoma when coverage was first requested on April 19, 2017. The undersigned therefore finds the requested TTFT (E0766) would have been covered under Medicare Part B. Accordingly, the Plan is required to provide retroactive coverage for TTFT (E0766) under Medicare Part C, dating back to the date of the Enrollee's coverage request (§1852(a) of the Act & 42 C.F.R. § 422.100)).

Conclusions of Law

Medical Mutual's MedMutual Advantage Classic HMO Plan must cover the requested tumor treatment field therapy (E0766) for the Enrollee under Medicare Part C, effective upon the date of the Enrollee's initial coverage request (April 19, 2017).

ORDER

The ~~Medicare Contractor is~~ DIRECTED to process the claim in accordance with this decision.

SEP 21 2017

Dated: _____

SO ORDERED.



David Mackintosh
Administrative Law Judge

³ Category 2A: is based upon lower-level evidence (than Category 1 evidence). There is uniform NCCN consensus that the intervention is appropriate (Source: National Comprehensive Cancer Network @ https://www.nccn.org/professionals/physician_gls/categories_of_consensus.asp).



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Cleveland Field Office
Cleveland, Ohio

Appeal of: **OSU PHYSICIAN GROUP**

ALJ Appeal No.: **1-6459444850**

Beneficiary: [REDACTED]

Medicare Part C

HICN: *******4179A**

Before: **David Mackintosh**
Administrative Law Judge

EXHIBIT LIST

EXHIBIT NUMBER	DESCRIPTION	NUMBER OF PAGES
1	Initial Redetermination, Reconsideration, Procedural Documents, Local Coverage Documents, and Evidence of Coverage	1-302
2	Medical Records/Evidence Received by CMS Contractors	1-142
3	Request for ALJ Hearing	1-2
4	OMHA Proceedings	1-6
5	New Evidence Received After Hearing	1-37(A)

Dated: August 24, 2017/MD



Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

Cleveland Field Office
200 Public Square, Suite 1300
Cleveland, OH 44114-2316
216-615-4000 (Main)
216-615-7544 (ALJ Mackintosh Team)
216-615-4175 (Fax)
866-236-5089 (Toll Free)

Date: September 22, 2017

NOVOCURE
ATTN: JORGE MORALES
195 COMMERCE WAY
PORTSMOUTH, NH 03801

NOTICE OF DECISION

Appellant: OSU PHYSICIAN GROUP

OMHA Appeal Number: 1-6459444850

Enclosed is the decision for the above case. This decision is based on the administrative record, including any evidence or testimony presented at the hearing, if one was held. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault. In addition, the decision may be reopened within 180 days of the decision for good cause. Good cause exists when there is new and material evidence that was not available or known at the time of the decision and may result in a different conclusion, or when the evidence that was considered clearly shows on its face that an obvious error was made at the time of the decision.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. Other parties may also appeal the decision. In addition, the Medicare Appeals Council may decide to review the decision on its own motion. If no party appeals the decision and the Medicare Appeals Council does not review the decision, the decision is binding on all parties and you and the other parties will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.

How much time do I have to file an appeal?

The Medicare Appeals Council must receive your written appeal **within 60 calendar days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 calendar days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing, except that a request for expedited review of a Part D decision may be made orally as described below. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree.

You may submit a written request for review to the Medicare Appeals Council using one of three available methods: mail, fax, or electronic filing (E-File). **Please do not submit your request for review using more than one method.** Regardless of how you file your appeal, **you must always send a copy of your written request for review to the other parties who received a copy of the decision.**

If you are filing a written request for review, you may use the enclosed *Request for Review* (Form DAB-101), or you may write a letter containing the following:

- The beneficiary's/enrollee's name (and telephone number for Part D appeals);
- The beneficiary's/enrollee's health insurance claim number;
- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's dismissal;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's decision (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

Filing by mail:

Mail your appeal and a copy of the enclosed decision to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Filing by fax:

Fax your appeal and a copy of the enclosed dismissal to (202) 565-0227.

Filing by computer:

Using your web browser, visit the Medicare Operations Division Electronic Filing System (MOD E-File) website at <https://dab.efile.hhs.gov/mod>.

To file a new appeal using MOD E-File, you will need to register by:

- (1) Clicking **Register** on the MOD E-File home page;
- (2) Entering the information requested on the "Register New Account" form; and
- (3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at <https://dab.efile.hhs.gov/mod/users/new>. You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party's representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

- (1) Logging into MOD E-File;
- (2) Clicking the **File New Appeal** menu button on the top right of the screen;
- (3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
- (4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the "File New Appeal – Medicare Operations Division" form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed decision. All documents should be submitted in Portable Document Format (PDF) whenever possible. Any document, including a Request for Review, will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.

Currently, the documents that may be filed electronically are the:

- (1) Request for Review;
- (2) Appointment of Representative form (OMB Form 0938-0950);
- (3) Copy of Administrative Law Judge or attorney adjudicator decision;
- (4) Memorandum or brief or other written statement in support of your appeal; and
- (5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D decision may be made by telephone to (866) 365-8204. You must provide the information listed in the bullet points above and a statement that

you are requesting an expedited review. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file. Please note that your request for review will only be expedited if the Part D drug has not already been furnished and the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at <http://www.hhs.gov/dab/>. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll free) if you have questions about filing an appeal.

cc:

OSU PHYSICIAN GROUP
460 E 10TH AVE
COLUMBUS, OH 43210

JOSEPHINE VALENTE
2060 E 9TH ST
CLEVELAND, OH 44115-1355

JAVIER GONZALEZ MD
OSU PHYSICIAN GROUP
460 E 10TH AVE
COLUMBUS, OH 43210

MAXIMUS
IRE Part C Appeals-ALJ
3750 Monroe Avenue, Suite 702
Pittsford, NY 14534-1302

Enclosures:

OMHA-152, Decision
DAB-101, Request for Review

REQUEST FOR REVIEW OF ADMINISTRATIVE LAW JUDGE (ALJ) MEDICARE DECISION / DISMISSAL

1. APPELLANT (the party requesting review)	2. ALJ APPEAL NUMBER (on the decision or dismissal)
3. BENEFICIARY*	4. HEALTH INSURANCE CLAIM NUMBER (HICN)*

*If the request involves multiple claims or multiple beneficiaries, attach a list of beneficiaries, HICNs, or other information to identify all claims being appealed.

5. PROVIDER, PRACTITIONER, OR SUPPLIER	6. SPECIFIC ITEM(S) OR SERVICE(S)
7. Medicare claim type: <input type="checkbox"/> Part A <input type="checkbox"/> Part B <input type="checkbox"/> Part C - Medicare Advantage <input type="checkbox"/> Part D - Medicare Prescription Drug Plan <input type="checkbox"/> Entitlement/enrollment for Part A or Part B	

8. Does this request involve authorization for an item or service that has not yet been furnished?

- ☐ Yes If Yes, skip to Block 8.
☐ No If No, Specific Dates of Service:

9. If the request involves authorization for a prescription drug under Medicare Part D, would application of the standard appellate timeframe seriously jeopardize the beneficiary's life, health, or ability to regain maximum function (as documented by a physician) such that expedited review is appropriate? ☐ Yes ☐ No

I request that the Medicare Appeals Council review the ALJ's ☐ decision or ☐ dismissal order [check one] dated _____. I disagree with the ALJ's action because (specify the parts of the ALJ's decision or dismissal you disagree with and why you think the ALJ was wrong):

(Attach additional sheets if you need more space)

PLEASE ATTACH A COPY OF THE ALJ DECISION OR DISMISSAL ORDER YOU ARE APPEALING.

DATE			DATE		
APPELLANT'S SIGNATURE (the party requesting review)			REPRESENTATIVE'S SIGNATURE (include signed appointment if not already submitted.)		
PRINT NAME			PRINT NAME		
ADDRESS			ADDRESS		
CITY, STATE, ZIP CODE			CITY, STATE, ZIP CODE		
TELEPHONE NUMBER	FAX NUMBER	E-MAIL	TELEPHONE NUMBER	FAX NUMBER	E-MAIL

(SEE FURTHER INSTRUCTIONS ON PAGE 2)

If you have additional evidence, submit it with this request for review. If you need more time, you must request an extension of time in writing now, explaining why you are unable to submit the evidence or legal argument now.

If you are a provider, supplier, or a beneficiary represented by a provider or supplier, and your case was reconsidered by a Qualified Independent Contractor (QIC), the Medicare Appeals Council will not consider new evidence related to issues the QIC has already considered unless you show that you have a good reason for submitting it for the first time to the Medicare Appeals Council.

IMPORTANT: Include the HICN and ALJ Appeal Number on any letter or other material you submit.

This request must be received within 60 calendar days after you receive the ALJ's decision or dismissal, unless we extend the time limit for good cause. We assume you received the decision or dismissal 5 calendar days after it was issued, unless you show you received it later. If this request will not be received within 65 calendar days from the date on the decision or dismissal order, please explain why on a separate sheet.

You must file your request for review in writing with the Medicare Appeals Council at:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

You may send the request for review by U.S. Mail, a common carrier such as FedEx, or by fax to (202) 565-0227. If you send a fax, please do not also mail a copy. **You must send a copy of your appeal to the other parties and indicate that all parties, to include all beneficiaries, have been copied on the request for review. For claims involving multiple beneficiaries, you may submit a copy of the cover letters issued or a spreadsheet of the beneficiaries and addresses who received a copy of the request for review.**

If you have any questions about your request for review or wish to request expedited review of a claim involving authorization of your prescription drug under Medicare Part D, you may call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100. You may also visit our web site at www.hhs.gov/dab for additional information on how to file your request for review.

PRIVACY ACT STATEMENT

The collection of information on this form is authorized by the Social Security Act (section 205(a) of title II, section 702 of title VII, section 1155 of Title XI, and sections 1852(g)(5), 1869(b)(1), 1871, 1872, and 1876(c)(5)(B) of title XVIII, as appropriate). The information provided will be used to further document your claim. Information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your claim. Information you furnish on this form may be disclosed by the Department of Health and Human Services or the Social Security Administration to another person or governmental agency only with respect to programs under the Social Security Act and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services, the Social Security Administration, or other agencies.



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City, Missouri

Appeal of: **NOVOCURE INC.**

OMHA Appeal No.: **1-2810933744**

Beneficiary:

Medicare: **Part B**

HICN: *******2539A**

Before: **Daniel H. Malvin**
U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, a **FULLY FAVORABLE** decision is entered for Novocure, Inc. ("Appellant"). Medicare coverage under Part B of Title XVIII of the Social Security Act ("Act") exists for the tumor treatment field therapy device, billed as E1399, for the dates of service of March 10, 2013, April 10, 2013, May 10, 2013 and June 10, 2013.

Procedural History

The Appellant provided a NovoTTF-100A ("NovoTTF") device to beneficiary ("Beneficiary") and billed Medicare for the items. The Medicare Administrative Contractor ("contractor") denied payment and upheld the denial of the appealed items in a redetermination decision. (Exh. 1, p. 3.) The Appellant subsequently submitted a request for reconsideration, and the Qualified Independent Contractor ("QIC"), C2C Solutions, Inc. ("C2C"), reviewed the Appellant's claim and issued an unfavorable reconsideration decision on July 25, 2014. (Exh. 1, pp. 1-6.)

On September 12, 2014, the Office of Medicare Hearings and Appeals ("OMHA") received the Appellant's request for an Administrative Law Judge ("ALJ") Hearing. (Exh. 3, pp. 3-4.)¹ On April 19, 2018, the Appellant appeared by telephone for an ALJ hearing through Stephanie Hales, of Sidley Austin, LLP, counsel for the Appellant. Also appearing for the Appellant were Justin Kelly, R.N., Senior Director of Health Policy, and Dan McCoy, Manager of Case Management, who were sworn in to testify as witnesses. There were no other appearances. Exhibits 1-4 were admitted into evidence without objection.

Issues

The issues before the Administrative Law Judge include all of the issues brought out in the initial determination, coverage determination, or organization determination; redetermination; or

¹ What appears to be another copy of the request for an ALJ hearing was received by OMHA on September 24, 2014. (Exh. 3, pp. 1-2.)

reconsideration that were not decided entirely in a party's favor, for the claims or other appealed matters specified in the request for hearing.

Findings of Fact

After careful consideration of the entire record and hearing testimony, this ALJ finds the following facts were established:

1. The Beneficiary, a female, was age 66 on the dates of service. (Exh. 2, p. 56.) She was diagnosed with glioblastoma. *Id.*
2. On September 15, 2011, the Beneficiary underwent a resection of a right parietal mass and pathology showed glioblastoma. (Exh. 2, p. 56.) The Beneficiary underwent a six-week course of radiation and temozolomide treatment from October 5, 2011 to November 18, 2011. *Id.* An MRI showed a recurrent tumor, so she began using bevacizumab on March 8, 2012. (Exh. 2, pp. 56-57.) There was no decrease in the tumor, so she began using Novocure Tumor Treatment Field therapy (NovoTTF) on April 10, 2012. *Id.* (See also Exh. 1, p. 43-46.)
3. On February 12, 2013, a Prescription and order form for the Beneficiary to continue to use the NovoTTF-100A and up to 40 disposable transducer arrays per month was completed for by Eric Wong. (Exh. 2, p. 1.) It stated the Beneficiary's diagnosis was brain tumor (ICD-9 191.9). *Id.*
4. On June 7, 2013, the Beneficiary's tumor progression was stable and her compliance with the NovoTTF device was 54%. (Exh. 2, pp. 56-58.) On July 3, 2013, her compliance was 62.75%. (Exh. 2, p. 55.) The Beneficiary remained on bevacizumab during these dates. (Exh. 2, pp. 53, 58.)
5. On August 2, 2013, the Beneficiary's compliance rate was 57.64% and she reported scalp redness a few weeks prior. (Exh. 2, p. 60.)
6. Novocure invoices for the dates of service at issue indicate that rental of the NovoTTF-100A device was \$5,500 per month. (Exh. 1, pp. 63-66.)
7. No advance beneficiary notice appears in the Record. (Exh. 1, p. 5.)
8. The Novocure summary states that the NovoTTF-100A device is a portable, wearable medical device that delivers tumor treating fields to a targeted tumor. (Exh. 2, p. 73.)
9. On April 8, 2011, the Food and Drug Administration (FDA) issued pre-market approval for the NovoTTF-100A system for treatment of adults with histologically-confirmed glioblastoma multiforme recurrence in the supratentorial region of the brain, to be used as a monotherapy after surgical and radiation options had been exhausted. (Exh. 2, p. 62.)
10. The National Comprehensive Care Network ("NCCN") Guidelines for Anaplastic Gliomas/Glioblastoma for 2013 listed alternating electric field therapy as a "2B" approved treatment for recurrent glioblastoma, after surgery if surgery was possible. (Hearing testimony.)² Category "2B" indicates the recommendation was based on a lower level of

² All hearing testimony and argument is recorded on a CD, which is part of the Record.

evidence and a majority of the NCCN panel had approved of the therapy, but it was not unanimous. *Id.*

11. On July 26, 2013, the Centers for Medicare and Medicaid Services (“CMS”) determined that the NovoTTF-100A system falls within the durable medical equipment category. (Exh. 1, p. 59.)
12. The Appellant presented several studies, including a published prospective, randomized, controlled study regarding tumor treatment field therapy on glioblastoma. (Exh. 2, pp. 115-125) (Roger Stupp et al., *NovoTTF-100A versus physician’s choice chemotherapy in recurrent glioblastoma: A randomized phase III trial of a novel treatment modality*, 48 European Journal of Cancer 2192-2202 (2012)). The studies submitted indicate that the prognosis of patients with recurrent glioblastoma is poor. *Id.* The tumor treatment field therapy employed by the NovoTTF interferes with the metaphase to anaphase transition in dividing tumor cells to prevent increase in brain tumor size. *Id.* Its effect on the tumor is similar to chemotherapy, but NovoTTF does not cause as many negative side effects as chemotherapy, and can be used if chemotherapy is exhausted. *Id.*
13. The recommended daily use is at least 18 hours a day, or 75%. (Exh. 2, p. 88.)

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with a reconsideration decision is entitled to a hearing before the Secretary of the Department of Health and Human Services, provided there is a sufficient amount in controversy and a request for hearing is filed within 60 days after the appellant receives the QIC’s reconsideration decision. Act § 1869(b)(1); 42 C.F.R. §§ 405.904(a), 405.1000, 405.1002, 405.1006. The authority of the Secretary to conduct such hearings has been delegated to Administrative Law Judges within the Office of Medicare Hearings and Appeals. 70 Fed. Reg. 36386, 36387 (June 23, 2005).

B. Scope of Review

The ALJ appeals process is governed by 42 C.F.R. §§ 405.1000–.1054. The ALJ considers all issues not decided entirely in appellant’s favor in the initial determination, redetermination and reconsideration decisions. 42 C.F.R. § 405.1032(a). In addition, an ALJ may consider certain new issues if the ALJ notifies all parties about the new issues before the start of the hearing. 42 C.F.R. § 405.1032(b).

C. Standard of Review

The ALJ is a finder-of-fact, who conducts a *de novo* review, and issues a decision based on the administrative record, including the hearing record. 42 C.F.R. § 405.1000(d) (2017). The appellant must furnish sufficient documentary evidence to support the claim and bears the burden

of proving the Medicare claim. *See* 42 C.F.R. § 424.5(a)(6); *Almy v. Sebelius*, 679 F.3d 297, 305 (4th Cir. 2012).

II. Principles of Law

A. Medicare Coverage for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (“DMEPOS”)

The Medicare program, Title XVIII of the Act, is administered through the Centers for Medicare and Medicaid Services (CMS), and Title 42 of the Code of Federal Regulations (C.F.R.) contains implementing regulations. The Supplementary Medical Insurance program (Part B of Title XVIII of the Act) provides coverage for a variety of medical services and supplies furnished by physicians, or by others, in connection with physicians’ services, for outpatient hospital services and for a number of other specific health-related items and services. *See* § 1832 of the Act; *see also* 42 C.F.R. § 410.10. The Act provides that Medicare part B pays for the rental or purchase of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (“DMEPOS”) if the equipment is used in the patient’s home or in an institution that is used as a home. *See, e.g.*, Act §§ 1832(a)(1), (a)(2)(B), (a)(2)(I), 1834(a)(13), 1861(s)(6); 42 C.F.R. § 410.3. *See also* Act § 1861(n) (defining “durable medical equipment”).

Durable medical equipment means equipment, furnished by a supplier or a home health agency that meets the following conditions:

- (1) Can withstand repeated use.
- (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- (3) Is primarily and customarily used to serve a medical purpose.
- (4) Generally is not useful to an individual in the absence of an illness or injury.
- (5) Is appropriate for use in the home.

42 C.F.R. § 414.202.

Expenses incurred by a beneficiary for the rental or purchases of durable medical equipment (DME) are reimbursable if the following three requirements are met:

- The equipment meets the definition of DME (§110.1);
- The equipment is necessary and reasonable for the treatment of the patient's illness or injury or to improve the functioning of his or her malformed body member (§110.1); and
- The equipment is used in the patient's home.

CMS, *Medicare Benefit Policy Manual (MBPM) (Internet-Only Manual Publ’n 100-02)* ch. 15, § 110 (Apr. 2013).

Notwithstanding any other provision of Title XVIII of the Act, no payment may be made for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Act § 1862(a)(1)(A). In addition, Section 1833(e) of the Act requires that all Medicare claims must be supported by sufficient information and documentation.

CMS contractors make coverage determinations on individual claims. The Medicare Program Integrity Manual states that contractors must determine whether the item or service in question is covered based on an LCD or the clinical judgment of the medical reviewer. CMS, *Medicare Program Integrity Manual (MPIM) (Internet-Only Manual Publ'n 100-08)* ch. 13, § 13.3 (May 2004). A service may be covered if it meets the same reasonable and necessary provisions for LCDs, as set out in chapter 13, section 13.5.1 of the MPIM.

Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
- Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
 - Furnished in a setting appropriate to the patient's medical needs and condition;
 - Ordered and furnished by qualified personnel;
 - One that meets, but does not exceed, the patient's medical need; and
 - At least as beneficial as an existing and available medically appropriate alternative.

MPIM, supra ch. 13, § 13.5.1. A contractor must base its medical necessity determination on strong evidence.

In order of preference, LCDs should be based on:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
- General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
 - Scientific data or research studies published in peer-reviewed medical journals;
 - Consensus of expert medical opinion (i.e., recognized authorities in the field); or
 - Medical opinion derived from consultations with medical associations or other health care experts.

MPIM, supra ch. 13, § 13.7.1. *See also Almy v. Sebelius*, 679 F.3d 297, 304-305 (4th Cir. 2012) (applying both the reasonable and necessary factors and the evidence requirements of the MPIM to individual adjudications by the Medicare Appeals Council as well as Medicare contractors). LCDs which challenge the standard of practice in a community and specify that an item or service is never reasonable and necessary shall be based on sufficient evidence to **convincingly refute** evidence presented in support of coverage. *MPIM, supra* ch. 13, § 13.7.1. However, “less stringent evidence is needed when allowing for individual consideration” *Id.*

B. Limitation on Liability

When Medicare coverage is precluded under Section 1862(a)(1)(A) of the Act, *i.e.*, the item was not reasonable and necessary, payment will be made, notwithstanding the preclusion, when neither the individual who received the item nor the person who furnished the item knew or could reasonably be expected to know that the item was not covered. This provision is commonly referred to as the “limitation on liability provision.” Act § 1879; 42 C.F.R. § 411.400(a). A Medicare provider has constructive knowledge of CMS manual instructions, bulletins, contractors’ written guides, directives, and standards of practice connected with Medicare reimbursement policies. 42 C.F.R. § 411.406(e); CMS, *Medicare Claims Processing Manual (MCPM) (Internet-Only Manual Publ’n 100-04)* ch. 30, § 40.1; CMS, *Medicare Financial Management Manual (MFMM) (Internet Only Manual Publ’n 100-06)*, ch. 3, § 90.1.H.

Analysis

The Enrollee’s request for an ALJ hearing was timely and satisfies jurisdictional requirements. The QIC denied coverage for the NovoTTF device because it found the documentation did not establish that the device was medically necessary for the Beneficiary and because it did not have documentation of the manufacturer’s retail price for the items. The Medicare contractor, similarly, did not find that the safety and efficacy of the device were established, so it found the device not medically reasonable and necessary. This ALJ finds that the NovoTTF device was medically reasonable and necessary for the Beneficiary for the dates of service under review.

In order for the NovoTTF (or any item of durable medical equipment) to be covered by Medicare, it must meet the definition of durable medical equipment, be used in the Beneficiary’s home, and necessary and reasonable for the treatment of the patient’s illness. To be found reasonable and necessary, it must be safe and effective, not experimental or investigational, and appropriate for the beneficiary. Determining whether the device is appropriate for the Beneficiary includes determining whether it is furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition. There is no applicable LCD for the dates of service under review. The NovoTTF device is durable medical equipment and was used in the Beneficiary’s home. The remaining question is whether it was reasonable and necessary for treatment of the Beneficiary’s glioblastoma.

The evidence presented demonstrates that the NovoTTF device is safe and effective and not experimental and investigational for treatment of individuals with glioblastoma multiforme under some circumstances. The FDA granted premarket approval for the NovoTTF device for treatment of adults with histologically-confirmed glioblastoma multiforme recurrence in the supratentorial region of the brain, to be used as a monotherapy after surgical and radiation options had been exhausted. The published studies also support such use. This ALJ finds that the use of NovoTTF to treat recurrent glioblastoma is supported by strong evidence, including published evidence derived from definitive randomized clinical trials, as well as general acceptance in the medical community, as illustrated by the NCCN guidelines recommending tumor treatment field therapy for treatment of recurrent glioblastoma. This ALJ finds that the NovoTTF treatment is reasonable and necessary for the dates of service, when used in accordance with in the parameters set out in the FDA approval.

The Record establishes that the Beneficiary was diagnosed with glioblastoma, that she underwent surgical resection of the parietal lobe tumor and then a six-week course of concurrent radiation and chemotherapy to treat the glioblastoma. The Record also shows that she had a recurrence of the glioblastoma tumor a few months later and attempted chemotherapy treatment with bevacizumab, but when no improvement was shown after one month of treatment with the chemotherapy, she began using the NovoTTF device in addition to the bevacizumab. She used the NovoTTF during the dates of service at issue with stable tumor progression. Thus, the diagnosis, location of tumor, exhaustion of chemoradiation treatment, and recurrence are all within the parameters that were approved by the FDA and supported by the published randomized controlled study. Accordingly, this ALJ finds that the NovoTTF device was reasonable and necessary for the Beneficiary during the dates of service.

In addition, this ALJ finds that the suggested retail price for the NovoTTF-100A device is established by the invoices submitted by the Appellant and included in the Record.

This ALJ finds that Medicare coverage exists for the NovoTTF-100A rental. Specifically, this ALJ finds that the NovoTTF device was medically necessary durable medical equipment for the Beneficiary. Since the ALJ has found that Medicare coverage exists, there is no remaining question of financial liability.

Conclusions of Law

This decision is **FULLY FAVORABLE** to the Appellant. Medicare Part B coverage exists for the NovoTTF-100A (E1399) provided to the Beneficiary with the dates of service of March 10, 2013, April 10, 2013, May 10, 2013 and June 10, 2013.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED

Dated: MAY 07 2018



Daniel H. Malvin
U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City, Missouri

Appeal of: **NOVOCURE INC.**

OMHA Appeal No.: **1-2822628391**

Beneficiary:

Medicare: **Part B**

HICN: *******1293A**

Before: **Daniel H. Malvin**
U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, a **FULLY FAVORABLE** decision is entered for Novocure, Inc. ("Appellant"). Medicare coverage under Part B of Title XVIII of the Social Security Act ("Act") exists for the NovoTTF-100A, billed as E1399, for the November 6, 2013 and December 6, 2013 dates of service, and for the transducer arrays for the device, billed as A9900, for the November 25, 2013 and December 21, 2013 dates of service.¹

Procedural History

The Appellant provided a NovoTTF-100A ("NovoTTF") device and transducer arrays to beneficiary ("Beneficiary") and billed Medicare for the items. The Medicare Administrative Contractor ("contractor") denied payment for the NovoTTF-100A and transducer arrays and upheld the denial of the appealed items in a redetermination decision. (See Exh. 1, p. 3.) The Appellant subsequently submitted a request for reconsideration, and the Qualified Independent Contractor ("QIC"), C2C Solutions, Inc. ("C2C"), reviewed the Appellant's claim and issued an unfavorable reconsideration decision on July 21, 2014. (Exh. 1, pp. 1-6.)

On September 5, 2014, the Office of Medicare Hearings and Appeals ("OMHA") received the Appellant's request for an Administrative Law Judge ("ALJ") Hearing. (Exh. 3, pp. 1-2.) On May 1, 2018, the Appellant appeared by telephone for an ALJ hearing through its appointed representative Stephanie Hales, Esq., of Sidley Austin, LLP, counsel for the Appellant. (See Exh. 4, p. 10.) Also appearing for the Appellant were its employees Justin Kelly, R.N., Senior Director of Health Policy, who was sworn in to testify as a witness, and Dan McCoy, Manager of Case Management. There were no other appearances, but CGS, the Contractor, submitted a position paper. (See Exh. 4, pp. 4-5.) Exhibits 1-4 were admitted into evidence without objection.

¹ On January 1, 2014, the new code HCPCS E0766, "electrical stimulation device used for cancer treatment, including all accessories" was created and tumor treatment field systems, consisting of the generator and the transducer arrays, are now billed under E0766. (Hearing testimony).

Issues

The issues before the Administrative Law Judge include all of the issues brought out in the initial determination, coverage determination, or organization determination; redetermination; or reconsideration that were not decided entirely in a party's favor, for the claims or other appealed matters specified in the request for hearing.

Findings of Fact

After careful consideration of the entire record and hearing testimony, this ALJ finds the following facts were established:

1. The Beneficiary, _____ on the dates of service. (Exh. 2, p. 45.) He was diagnosed with glioblastoma multiforme. (Exh. 2, p. 47.)
2. The Beneficiary underwent a left temporal craniotomy on September 5, 2013 for resection of the glioblastoma tumor. (Exh. 2, pp. 45-46.)
3. He received concurrent radiation therapy with Temodar (temozolomide) chemotherapy beginning on September 26, 2012. (Exh. 2, pp. 45-46.) Avastin (bevacizumab) chemotherapy was added on October 8, 2012. *Id.*
4. The Beneficiary's November 2012 imaging was stable, and he began the first of nine cycles of Temodar chemotherapy. *Id.* He experienced a recurrence in January 2013. *Id.* The Beneficiary started a Temodar cycle on July 19, 2013 and was due to start another on August 16, 2013, but it was delayed for a week pending a new MRI and follow-up with the Beneficiary's doctor. *Id.*
5. On August 21, 2013, the Beneficiary's MRI showed tumor progression. (Exh. 2, pp. 49-50.) He was experiencing chemotherapy-induced thrombocytopenia, so his Avastin was held until his blood counts improved. *Id.* The Beneficiary and his doctor, Ashley Sumrall, M.D., decided to pursue NovoTTF therapy. *Id.*
6. On August 22, 2013, Dr. Sumrall prescribed a NovoTTF-100A device and transducer arrays for the Beneficiary. (Exh. 2, p. 6.) She listed "GBM" (glioblastoma multiforme) as his diagnosis. *Id.*
7. The Beneficiary received the NovoTTF-100A device and related accessories on September 6, 2013. (Exh. 1, p. 43.) The Appellant shipped transducer arrays to the Beneficiary, who was located in South Carolina, on November 25, 2013 and December 20, 2013. (Exh. 2, pp. 1, 3.)
8. The Beneficiary's November 14, 2013 MRI brain scan showed progression of the disease around the resection cavity. (Exh. 2, pp. 21-22.) He continued with NovoTTF therapy and Avastin, and was going to add in additional chemotherapy drugs Gleevec and Cytosan. (Exh. 2, p. 32.)
9. In a letter of November 7, 2013 requesting redetermination of an earlier claim, Dr. Sumrall wrote that given the aggressive nature and extremely limited treatment options of the Beneficiary's glioblastoma, NovoTTF was the best FDA-approved treatment option. (Exh. 1, pp. 36-38.)

10. The invoice from Novocure for the date of service indicates the transducer arrays cost \$14,000 for a box of 40, which is about a month's supply. (Exh. 1, pp. 32, 34.) A one-month rental of the NovoTTF device itself was \$5,500. (Exh. 1, pp. 33, 35.)
11. No advance beneficiary notice appears in the Record. (*See* Exh. 2.)
12. On April 8, 2011, the Food and Drug Administration (FDA) issued pre-market approval for the NovoTTF-100A system for treatment of adults with histologically-confirmed glioblastoma multiforme recurrence, to be used as a monotherapy after surgical and radiation options had been exhausted. (Exh. 2, p. 51.)
13. The Novocure summary states that the NovoTTF-100A device is a portable, wearable medical device that delivers tumor treating fields to a targeted tumor. (Exh. 2, p. 62.)
14. The National Comprehensive Care Network ("NCCN") Guidelines for Anaplastic Gliomas/Glioblastoma for 2013 listed alternating electric field therapy as a "2B" approved treatment for recurrent glioblastoma, after surgery if surgery was possible. (Exh. 2, p. 170; Hearing testimony.)² Category "2B" indicates the recommendation was based on a lower level of evidence and a majority of the NCCN panel had approved of the therapy, but it was not unanimous. (Hearing testimony.)
15. The Appellant presented several studies, including a published prospective, randomized, controlled study regarding tumor treatment field therapy on glioblastoma. (Exh. 2, pp. 104-114) (Roger Stupp et al., *NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma: A randomized phase III trial of a novel treatment modality*, 48 European Journal of Cancer 2192-2202 (2012)). The studies submitted indicate that the prognosis of patients with recurrent glioblastoma is poor. *Id.* The tumor treatment field therapy employed by the NovoTTF interferes with the metaphase to anaphase transition in dividing tumor cells to prevent increase in brain tumor size. *Id.* Its effect on the tumor is similar to chemotherapy, but NovoTTF does not cause as many negative side effects as chemotherapy, and can be used if chemotherapy is exhausted. *Id.*
16. NovoTTF-100A is an item of durable medical equipment. (Exh. 4, p. 4; *see also* Exh. 1, p. 57.)

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with a reconsideration decision is entitled to a hearing before the Secretary of the Department of Health and Human Services, provided there is a sufficient amount in controversy and a request for hearing is filed within 60 days after the appellant receives the QIC's reconsideration decision. Act § 1869(b)(1); 42 C.F.R. §§ 405.904(a), 405.1000, 405.1002, 405.1006. The authority of the Secretary to conduct such hearings has been delegated to

² All hearing testimony and argument is recorded on a CD, which is part of the Record.

Administrative Law Judges within the Office of Medicare Hearings and Appeals. 70 Fed. Reg. 36386, 36387 (June 23, 2005).

B. Scope of Review

The ALJ appeals process is governed by 42 C.F.R. §§ 405.1000–.1054. The ALJ considers all issues not decided entirely in appellant's favor in the initial determination, redetermination and reconsideration decisions. 42 C.F.R. § 405.1032(a). In addition, an ALJ may consider certain new issues if the ALJ notifies all parties about the new issues before the start of the hearing. 42 C.F.R. § 405.1032(b).

C. Standard of Review

The ALJ is a finder-of-fact, who conducts a *de novo* review, and issues a decision based on the administrative record, including the hearing record. 42 C.F.R. § 405.1000(d) (2017). The appellant must furnish sufficient documentary evidence to support the claim and bears the burden of proving the Medicare claim. *See* 42 C.F.R. § 424.5(a)(6); *Almy v. Sebelius*, 679 F.3d 297, 305 (4th Cir. 2012).

II. Principles of Law

A. Medicare Coverage for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS")

The Medicare program, Title XVIII of the Act, is administered through the Centers for Medicare and Medicaid Services (CMS), and Title 42 of the Code of Federal Regulations (C.F.R.) contains implementing regulations. The Supplementary Medical Insurance program (Part B of Title XVIII of the Act) provides coverage for a variety of medical services and supplies furnished by physicians, or by others, in connection with physicians' services, for outpatient hospital services and for a number of other specific health-related items and services. *See* § 1832 of the Act; *see also* 42 C.F.R. § 410.10. The Act provides that Medicare part B pays for the rental or purchase of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") if the equipment is used in the patient's home or in an institution that is used as a home. *See, e.g.*, Act §§ 1832(a)(1), (a)(2)(B), (a)(2)(I), 1834(a)(13), 1861(s)(6); 42 C.F.R. § 410.3. *See also* Act § 1861(n) (defining "durable medical equipment").

Durable medical equipment means equipment, furnished by a supplier or a home health agency that meets the following conditions:

- (1) Can withstand repeated use.
- (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- (3) Is primarily and customarily used to serve a medical purpose.
- (4) Generally is not useful to an individual in the absence of an illness or injury.
- (5) Is appropriate for use in the home.

42 C.F.R. § 414.202.

Expenses incurred by a beneficiary for the rental or purchases of durable medical equipment (DME) are reimbursable if the following three requirements are met:

- The equipment meets the definition of DME (§110.1);
- The equipment is necessary and reasonable for the treatment of the patient's illness or injury or to improve the functioning of his or her malformed body member (§110.1); and
- The equipment is used in the patient's home.

CMS, *Medicare Benefit Policy Manual (MBPM) (Internet-Only Manual Publ'n 100-02)* ch. 15, § 110 (Apr. 2013).

Notwithstanding any other provision of Title XVIII of the Act, no payment may be made for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Act § 1862(a)(1)(A). In addition, Section 1833(e) of the Act requires that all Medicare claims must be supported by sufficient information and documentation.

CMS contractors make coverage determinations on individual claims. The Medicare Program Integrity Manual states that contractors must determine whether the item or service in question is covered based on an LCD or the clinical judgment of the medical reviewer. CMS, *Medicare Program Integrity Manual (MPIM) (Internet-Only Manual Publ'n 100-08)* ch. 13, § 13.3 (May 2004). A service may be covered if it meets the same reasonable and necessary provisions for LCDs, as set out in chapter 13, section 13.5.1 of the MPIM. *Id.*

Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
- Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
 - Furnished in a setting appropriate to the patient's medical needs and condition;
 - Ordered and furnished by qualified personnel;
 - One that meets, but does not exceed, the patient's medical need; and
 - At least as beneficial as an existing and available medically appropriate alternative.

MPIM, supra ch. 13, § 13.5.1. A contractor must base its medical necessity determination on strong evidence.

In order of preference, LCDs should be based on:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and

- General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
 - Scientific data or research studies published in peer-reviewed medical journals;
 - Consensus of expert medical opinion (i.e., recognized authorities in the field); or
 - Medical opinion derived from consultations with medical associations or other health care experts.

MPIM, *supra* ch. 13, § 13.7.1. See also *Almy v. Sebelius*, 679 F.3d 297, 304-305 (4th Cir. 2012) (applying both the reasonable and necessary factors and the evidence requirements of the MPIM to individual adjudications by the Medicare Appeals Council as well as Medicare contractors). LCDs which challenge the standard of practice in a community and specify that an item or service is never reasonable and necessary shall be based on sufficient evidence to **convincingly refute** evidence presented in support of coverage. *MPIM*, *supra* ch. 13, § 13.7.1. However, “less stringent evidence is needed when allowing for individual consideration . . .” *Id.*

B. Limitation on Liability

When Medicare coverage is precluded under Section 1862(a)(1)(A) of the Act, *i.e.*, the item was not reasonable and necessary, payment will be made, notwithstanding the preclusion, when neither the individual who received the item nor the person who furnished the item knew or could reasonably be expected to know that the item was not covered. This provision is commonly referred to as the “limitation on liability provision.” Act § 1879; 42 C.F.R. § 411.400(a). A Medicare provider has constructive knowledge of CMS manual instructions, bulletins, contractors’ written guides, directives, and standards of practice connected with Medicare reimbursement policies. 42 C.F.R. § 411.406(e); CMS, *Medicare Claims Processing Manual (MCPM) (Internet-Only Manual Publ’n 100-04)* ch. 30, § 40.1; CMS, *Medicare Financial Management Manual (MFMM) (Internet Only Manual Publ’n 100-06)*, ch. 3, § 90.1.H.

Analysis

The Enrollee’s request for an ALJ hearing was timely and satisfies jurisdictional requirements. The QIC denied coverage of the NovoTTF-100A device and transducer arrays because it did not find sufficient information showing the effects of the TTF therapy for the Beneficiary, and because it did not have documentation of the manufacturer’s retail price for the item. This ALJ finds that the manufacturer’s price is included in the Record, and the Appellant has established that the NovoTTF device and transducer arrays are medically necessary to treat the Beneficiary’s condition.

In order for the NovoTTF (or any item of durable medical equipment) to be covered by Medicare, it must be necessary and reasonable for the treatment of the patient’s illness. That means it must be safe and effective, not experimental or investigational, and appropriate for the beneficiary. To determine whether the NovoTTF therapy is appropriate for the Beneficiary includes determining whether it is furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition. There is no applicable LCD for the dates of service under review. The NovoTTF device is durable medical equipment and was used in the Beneficiary’s

home. The remaining question is whether it was reasonable and necessary for treatment of the Beneficiary's glioblastoma.

The evidence presented demonstrates that the NovoTTF device is safe and effective and not experimental and investigational for treatment of individuals with glioblastoma multiforme under some circumstances. The FDA granted premarket approval for the NovoTTF device for treatment of adults with histologically-confirmed glioblastoma multiforme recurrence in the supratentorial region of the brain, to be used as a monotherapy after surgical and radiation options had been exhausted. The published studies also support such use. This ALJ finds that the use of NovoTTF to treat recurrent glioblastoma is supported by strong evidence, including published evidence derived from definitive randomized clinical trials, as well as general acceptance in the medical community, as illustrated by the NCCN guidelines recommending tumor treatment field therapy for treatment of recurrent glioblastoma. This ALJ finds that the NovoTTF treatment is reasonable and necessary for the dates of service, when used in accordance with the parameters set out in the FDA approval.

The Record establishes that the Beneficiary had glioblastoma multiforme and had undergone surgical resection of the tumor and subsequent concurrent chemotherapy and radiation. He had a recurrence of the glioblastoma and began receiving additional chemotherapy, but his August 2013 MRI showed additional tumor progression. At that point his doctor prescribed the NovoTTF device. She stated in her letter that NovoTTF was the best FDA-approved treatment option for the Beneficiary's glioblastoma. Thus, the diagnosis, location of tumor, exhaustion of chemoradiation treatment, and recurrence are all within the parameters that were approved by the FDA and supported by the published randomized controlled study. Accordingly, this ALJ finds that the NovoTTF device was reasonable and necessary for the Beneficiary during the dates of service.

In addition, this ALJ finds that the suggested retail price for the NovoTTF-100A device and the transducer arrays is established by the invoices submitted by the Appellant and included in the Record.

This ALJ finds that Medicare coverage exists for the NovoTTF-100A rental. Specifically, this ALJ finds that the NovoTTF device was medically necessary durable medical equipment for the Beneficiary for treatment of his recurrent glioblastoma. Since the ALJ has found that Medicare coverage exists, there is no remaining question of financial liability.

Conclusions of Law

This decision is **FULLY FAVORABLE** to the Appellant. Medicare Part B coverage exists for the NovoTTF-100A (E1399) for the November 6, 2013 and December 6, 2013 dates of service, or for the transducer arrays for the device (A9900) for the November 25, 2013 and December 21, 2013 dates of service.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED

A handwritten signature in black ink, appearing to read "Daniel H. Malvin", written over a horizontal line.

Daniel H. Malvin
U.S. Administrative Law Judge

Dated: MAY 23 2018



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City, Missouri

Appeal of:

OMHA Appeal No.: **1-7153360640**

Enrollee:

Medicare: **Part C**

HICN: *******6690A**

Before: **Daniel H. Malvin**
U.S. Administrative Law Judge

DECISION

After carefully considering the evidence in the administrative record and arguments presented at the hearing, a **FULLY FAVORABLE** decision is entered for (‘‘Enrollee’’). The Part C Plan is required to cover Optune plus transducers (E0766) under Medicare Part C under Title XVIII of the Social Security Act (‘‘Act’’).

Procedural History

The Enrollee is enrolled in a Medicare Advantage plan called TexanPlus Classic HMO with SelectCare of Texas, Inc. (‘‘Plan’’). (See, e.g., Exh. 1, pp. 26, 76.) The Enrollee requested that the Plan preapprove coverage for Optune tumor treatment field therapy (TTFT) to treat the Enrollee’s glioblastoma. (Exh. 1, p. 24.) The Plan denied the Enrollee’s initial request for coverage and denied coverage in his subsequent appeal. (Exh. 1, pp. 20-21, 39, 45-46.) The Independent Review Entity (‘‘IRE’’), MAXIMUS Federal Services (‘‘MAXIMUS’’), reviewed the Enrollee’s claim and issued an unfavorable reconsideration decision on November 21, 2017. (Exh. 1, pp. 3-5.)

On, January 4, 2018, the Enrollee’s request for an Administrative Law Judge (‘‘ALJ’’) Hearing was received by MAXIMUS.¹ (Exh. 3, p. 1.) On February 12, 2018, the ALJ conducted a telephone hearing.² The Appellant/Enrollee appeared through Sean McGartland, Case Manager for Novocure, who was the Appellant’s appointed representative. (See Exh. 4, p. 16.) Novocure also appeared through Justin Kelly, R.N., senior director of health policy, and Stephanie Hales, Esq., of the law firm of Sidley Austin, counsel for Novocure. The Plan appeared through Donald Thomas, Appeals and Grievance Team Lead for Universal American, and Manisi Kekan, M.D., Medical Director of SelectCare of Texas. Mr. Kelly, Mr. Thomas and Dr. Kekan were sworn in as witnesses. Exhibits 1-4 were admitted into evidence without objection. The Record was held open until February 14, 2018 at 5:00 p.m. CST for submission of updated medical records for the

¹ MAXIMUS was the entity specified in the IRE’s reconsideration decision to receive the request for ALJ hearing. (Exh. 1, p. 3.)

² A CD containing an audio recording of this hearing is included with the record.

Enrollee, which were timely received and admitted to the record as Exhibit 5. Upon receipt of the records, the Record was closed.

Issues

The issues before the Administrative Law Judge include all of the issues brought out in the initial determination, coverage determination, or organization determination; redetermination; or reconsideration that were not decided entirely in a party's favor, for the claims or other appealed matters specified in the request for hearing.

Findings of Fact

After careful consideration of the entire record and hearing testimony, the following facts were established:

1. The Enrollee, a 72 year-old male, has a glioblastoma multiforme brain tumor. (Exh. 2, pp. 5-8.)
2. The Enrollee was diagnosed with glioblastoma in late 2016. (Exh. 2, pp. 5-8.) He underwent a craniotomy and resection of the tumor on November 15, 2016. *Id.* Following surgery, the Enrollee underwent radiation therapy, which was completed on January 24, 2017. *Id.* He also is treated with Temozolomide, a chemotherapy drug. *Id.*
3. The Enrollee has been on Optune therapy since February of 2017. (Hearing testimony.) Optune tumor treatment field therapy is a battery-operated device that produces alternating electrical fields through four transducer arrays the patient places on their scalp. (Exh. 2, p. 63, hearing testimony.) The tumor treatment fields disrupt the rapid cell division of cancer cells. (Exh. 2, p. 63.)
4. Pre-market FDA approval was granted to Optune for recurrent glioblastoma in April 2011. (Exh. 1, p. 37.) The pre-market approval was based upon a randomized controlled study that showed patients treated with Optune had overall survival and progression-free survival rates comparable to those treated with chemotherapy, with minimal toxicity and an improvement in patient quality of life compared to chemotherapy. (Exh. 1, p. 37.) The 2011 pre-market approval was for use of tumor treatment field therapy by itself, instead of chemotherapy. (*Id.*; hearing testimony).
5. The National Comprehensive Cancer Network (NCCN) guidelines, version 1.2016, references alternating electric field therapy in conjunction with radiation therapy and temozolomide as a category 2A recommended treatment for glioblastoma. (Exh. 2, pp. 43-46.) NCCN category 2A is defined as: "Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate."³
6. The Journal of the American Medical Association published a study of maintenance therapy for newly-diagnosed glioblastoma with tumor-treating fields plus temozolomide

³ National Comprehensive Cancer Network. (2018.) *NCCN Categories of Evidence and Consensus*. Retrieved February 22, 2018 from https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx.

versus temozolomide alone on December 15, 2015. (R. Stupp, et al, *Maintenance Therapy with Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma: A Randomized Clinical Trial*, 314 *Journal of the American Medical Association* 2535 (2015)). (Exh. 2, pp. 48-56.) The controlled, randomized trial with 695 patients concluded that progression-free survival and overall survival were greater among the patients receiving both tumor treating fields and temozolomide than for patients receiving only temozolomide. (Exh. 2, pp. 47-48.) Based on the interim analysis of the trial, the study was concluded early. (Exh. 2, p. 53.) The interim analysis showed that adding tumor treatment fields to temozolomide chemotherapy “significantly prolonged progression-free and overall survival.” (Exh. 2, p. 55.)

7. In a letter dated December 30, 2016, the Enrollee’s Neuro-oncologist, M.D., requested coverage of the Optune in combination with temozolomide because it was currently the best option for treating the Enrollee’s glioblastoma. (Exh. 1, p. 36.) Dr. _____ wrote that glioblastoma has limited available treatment options, and at Methodist Neurological Institute, where he works, Optune had been used with excellent outcomes. (Exh. 1, pp. 36-37.)
8. A prior ALJ decision dated April 20, 2017, directed the Part C Plan to pay for the Enrollee’s Optune therapy for prior dates of service. (See Exh. 1, pp. 57-62.) Select Care paid for the Enrollee’s treatment through November 2017. (Hearing testimony.)
9. On May 12, 2017, the Enrollee’s treating physician prescribed six months of Optune therapy for the Enrollee. (Exh. 2, p. 103.) A request for pre-authorization from the Enrollee’s health plan was made on or about July 31, 2017. (Exh. 2, p. 104.)
10. On June 21, 2017, the Enrollee’s MRI showed a focal area of increased signal intensity along the right lateral ventricle, which could represent either postoperative changes or residual neoplasm. (Exh. 2, p. 19.)
11. An MRI completed October 26, 2017 indicated the Enrollee’s tumor was stable. (Exh. 2, pp. 79-82.)
12. On January 3, 2018, the Enrollee was seen by Dr. _____ (Exh. 5, pp. 7-10.) The doctor recorded that the Enrollee had been using TTFT 80% of the time with only mild skin irritation. *Id.* The Enrollee was feeling well and had hosted his family at Christmas. *Id.* An MRI from January 3, 2018 was described as “stable” with post-treatment changes. *Id.* The Enrollee and his doctor discussed long-term benefits of TTFT and the Enrollee was motivated to continue using it. *Id.*
13. The Enrollee reported some fatigue, however his condition has remained generally stable when recorded by his neuro-oncologist. (See Exh. 2, pp. 5-16.)
14. The Plan denied the requested Optune plus transducers solely because the applicable Local Coverage Determination precluded it. (Hearing testimony).

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with a reconsideration decision is entitled to a hearing before the Secretary of the Department of Health and Human Services, provided there is a sufficient amount in controversy and a request for hearing is filed within 60 days after the Enrollee receives the reconsideration decision. Act § 1869(b)(1); 42 C.F.R. §§ 405.904(a), 405.1000, 405.1002, 405.1006; 422.562(d), 422.600, 422.602. The authority of the Secretary to conduct such hearings has been delegated to Administrative Law Judges within the Office of Medicare Hearings and Appeals. 70 Fed. Reg. 36386, 36387 (June 23, 2005).

B. Scope of Review

The ALJ appeals process is governed by 42 C.F.R. §§ 405.1000–405.1054; 422.562(d), 422.600, 422.602. The ALJ considers all issues not decided entirely in Enrollee's favor in the initial determination, redetermination and reconsideration decisions. 42 C.F.R. § 405.1032(a). In addition, an ALJ may consider certain new issues if the ALJ notifies all parties about the new issues before the start of the hearing. 42 C.F.R. § 405.1032(b).

C. Standard of Review

The ALJ is a finder-of-fact, who conducts a *de novo* review, and issues a decision based on the administrative record, including the hearing record. 42 C.F.R. § 405.1000(d) (2017). Enrollee must furnish sufficient documentary evidence to support the claim and bears the burden of proving the Medicare claim. *See* 42 C.F.R. § 424.5(a)(6); *Amy v. Sebelius*, 679 F.3d 297, 305 (4th Cir. 2012).

II. Principles of Law

Under Medicare Part C, a Medicare Advantage Plan must pay for those items and services (other than hospice benefits) that are available under Medicare Parts A and B or only Part B according to the corresponding enrollment in coverage. Act § 1852; 42 C.F.R. §§ 422.100(a), (c)(1). An enrollee may also purchase supplemental benefits. 42 C.F.R. § 422.100(c). A Medicare Advantage Plan must provide plan enrollees with coverage of their entitled benefits by “furnishing those benefits directly or through arrangements, or by paying for the benefits.” 42 C.F.R. § 422.101(a).

Under Medicare Part B, a beneficiary is entitled to have payment made on his behalf for medical and other health services. Act § 1832(a)(1). The Act provides that Medicare pays for the rental or purchase of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (“DMEPOS”) if the equipment is used in the patient's home or in an institution that is used as a home. *See, e.g.*, Act §§ 1832(a)(1), (a)(2)(B), (a)(2)(I), 1834(a)(13), 1861(s)(6); 42 C.F.R. § 410.3. *See also* Act § 1861(n) (defining “durable medical equipment”).

Notwithstanding any other provision of Title XVIII of the Act, no payment may be made for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury

or to improve the functioning of a malformed body member. Act § 1862(a)(1)(A). All Medicare claims must be supported by sufficient information and documentation. Act § 1833(e).

A Medicare Advantage Plan must comply with: national coverage determinations by the Center for Medicare and Medicaid Services (CMS), Part A and B general coverage guidelines from manuals and instructions (unless they conflict with Part C regulations or instructions), and written coverage decisions of local Medicare contractors with jurisdiction. 42 C.F.R. § 422.101(b). ALJs are not bound by Medicare program guidance, such as Local Coverage Determinations (LCDs), program memoranda and manual instructions, but ALJs “will give substantial deference to these policies if they are applicable to a particular case.” 42 C.F.R. § 405.1062(a).

The applicable LCD is LCD L34823, which states, “Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.” CGS Administrators, LLC, Local Coverage Determination L34823: Tumor Treatment Field Therapy (LCD L34823) (Jan. 1, 2017). This LCD also references some general documentation requirements for durable medical equipment (DME) and references a policy article. The policy article explains:

Code E0766 describes devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers.

This code is inclusive of all associated supplies necessary for the effective use of code E0766 including, but not limited to, transducers/surface electrodes, lead wires, adhesive patches, connectors, conductive gel and skin preps.

CGS Administrators, LLC, Policy Article A52711: Tumor Treatment Field Therapy (Article A52711) (Jan. 1, 2017).

When a Contractor drafts an LCD, it must comply with CMS’s guidance set out in the Medicare Program Integrity Manual:

Contractor LCDs shall be based on the strongest evidence available. The extent and quality of supporting evidence is key to defending challenges to LCDs. The initial action in gathering evidence to support LCDs shall always be a search of published scientific literature for any available evidence pertaining to the item or service in question. In order of preference, LCDs should be based on:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
- General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
 - o Scientific data or research studies published in peer-reviewed medical journals;
 - o Consensus of expert medical opinion (i.e., recognized authorities in the field); or
 - o Medical opinion derived from consultations with medical associations or other health care experts.

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

LCDs which challenge the standard of practice in a community and specify that an item or service is never reasonable and necessary shall be based on sufficient evidence to convincingly refute evidence presented in support of coverage.

Less stringent evidence is needed when allowing for individual consideration.

CMS, *Medicare Program Integrity Manual (MPIM) (Internet-Only Publ'n 100-08)* ch. 13, § 13.7.1 (Jan. 2015).

Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
 - o Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
 - o Furnished in a setting appropriate to the patient's medical needs and condition;
 - o Ordered and furnished by qualified personnel;
 - o One that meets, but does not exceed, the patient's medical need; and
 - o At least as beneficial as an existing and available medically appropriate alternative.

MPIM, supra Ch. 13, § 13.5.1 (Jan. 2015).

The Plan's Evidence of Coverage states that the Plan must cover all services covered by Original Medicare and must follow Original Medicare's coverage rules. (Exh. 1, p. 116.) It says that generally, the Plan will cover medical care as long as it is included in the Medical Benefits Chart, it is medically necessary, and the Enrollee has a network primary care provider overseeing his or

her care. *Id.* The Plan requires prior authorization before it covers Durable Medical Equipment (DME). (Exh. 1, pp. 140-41.) Durable Medical Equipment is defined by the plan as certain medical equipment ordered by a doctor for medical reasons, and gives the examples of walkers, wheelchairs, or hospital beds. (Exh. 1, p. 298.) The Plan covers all medically necessary durable medical equipment covered by Original Medicare. (Exh. 1, p. 141.) The Plan does not cover experimental medical and surgical procedures, equipment or medications. (Exh. 1, pp. 167-68.)

Analysis

The Enrollee's request for an ALJ hearing was timely and satisfies jurisdictional requirements. The evidence in this case supports a finding that the Plan must cover the Optune tumor treatment field therapy under the Part C Plan.

The Plan denied coverage of the Optune tumor treatment field therapy because it is bound by the LCD, not on the grounds that the tumor treatment field therapy (TTFT) is not medically necessary for this individual Enrollee. Although the LCD sets out a categorical denial of TTFT, it does not cite any research or other information that leads to the Contractor's conclusion that TTFT is never medically necessary. Contractor LCDs should be based on the strongest evidence available, including randomized clinical studies. CMS guidance in the Medicare Program Integrity Manual states that LCDs which challenge the standard of practice in a community and specify that an item or service is never reasonable and necessary shall be based on sufficient evidence to **convincingly refute** evidence presented in support of coverage. The LCD addressing TTFT was issued in October 2015. Revisions were issued on July 1, 2016, which include updates to the links for sources of information and basis of the decision. LCD L34823 (Jan. 1, 2017). In the most recent version of this LCD, effective January 1, 2017, under the heading "Sources of Information and Basis for Decision[.]" the term "N/A" appears. Research on TTFT has continued, however, leading to approval of TTFT for treatment of newly diagnosed glioblastoma in December of 2015. Randomized controlled studies have concluded that the use of Optune TTFT in conjunction with temozolomide chemotherapy is an effective and safe treatment for glioblastoma. In addition, the therapy is generally accepted in the medical community, as indicated by its inclusion in therapy recommendations from the National Comprehensive Cancer Network (NCCN). This ALJ gives the applicable LCD (LCD L34823) substantial deference, but declines to apply this LCD in this case, finding that the evidence presented by the Appellant in support of the use of TTFT outweighs the LCD, which, in the current version effective January 1, 2017, cites no evidence whatsoever in support of its absolute denial of coverage for TTFT.⁴

This ALJ finds that the Optune tumor treatment field therapy is medically reasonable and necessary for this Enrollee. The Enrollee is diagnosed with glioblastoma multiforme. He has already undergone surgical resection of the tumor and radiation therapy. He is on chemotherapy with temozolomide, and has used the Optune tumor treatment field therapy with good result. The treatment plan for the Enrollee is the same one that was reported on in the December 2015 study, which showed improved survival rates. The Plan did not deny coverage of the TTFT for lack of medical necessity. The therapy was only denied because it is disallowed by the LCD. This ALJ finds that the Optune device plus transducers (E0766) is durable medical equipment that is

⁴ This ALJ is declining to follow this LCD based upon the specific facts, circumstances, and evidence presented in the case at issue. This should not be construed as a finding that this LCD is not valid. See 42 C.F.R. § 405.1062(b), (c) ("An ALJ . . . may not set aside or review the validity of an . . . LCD for purposes of a claim appeal").

medically reasonable and necessary for this Enrollee and must be covered by the Medicare Part C Plan.

Conclusions of Law

This decision is **FULLY FAVORABLE** to the Enrollee. The Plan is required to grant prior approval for and cover the Optune tumor treatment field therapy (E0766) under the Enrollee's Part C Plan.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED

Dated: FEB 23 2018

A handwritten signature in black ink, appearing to read 'D. Malvin', written over a horizontal line.

Daniel H. Malvin
U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City, Missouri

Appeal of:	OMHA Appeal No.: 1-7560040883
Enrollee:	Medicare: Part C
Medicare No.:	Before: Daniel H. Malvin U.S. Administrative Law Judge

DECISION

After carefully considering the evidence in the administrative record and arguments presented at the hearing, a **FULLY FAVORABLE** decision is entered for: [redacted] ("Enrollee"). The Part C Plan is required to cover Tumor Treatment Field Therapy (TTFT) under Medicare Part C under Title XVIII of the Social Security Act ("Act").

Procedural History

The Enrollee is enrolled in a Part C Medicare Advantage plan with BCBS of Michigan Mutual Insurance Company ("Plan"). (See Exh. 1, pp. 2, 61.) The Enrollee requested that the Plan preapprove coverage for an Optune tumor treatment device and transducer arrays to treat the Enrollee's glioblastoma. (Exh. 1, p. 55.) The Plan denied the Enrollee's initial request for coverage and denied coverage in his subsequent appeal. (Exh. 1, pp. 32-33, 55-56.) The Independent Review Entity ("IRE"), MAXIMUS Federal Services ("MAXIMUS"), reviewed the Enrollee's claim and issued an unfavorable reconsideration decision on May 14, 2018. (Exh. 1, pp. 3-5.)

On May 29, 2018, the Enrollee's request for an Administrative Law Judge ("ALJ") Hearing was received by the Office of Medicare Hearings and Appeals. (Exh. 3, p. 1.) On July 24, 2018, the ALJ conducted a telephone hearing.¹ The Appellant/Enrollee appeared through Dan McCoy, Manager of Case Management for Novocure, who was the Appellant's appointed representative. (See Exh. 1, p. 16.) Novocure also appeared by Julie Miles, RN, Clinical Appeals Specialist, and Stephanie Hales, Esq., Sidley Austin, counsel for Novocure. The Part C Plan was not notified of the July hearing, so the hearing was continued.

On August 15, 2018, the Appellant appeared by telephone through Dan McCoy. Also appearing were Julie Miles and Stephanie Hales on behalf of Novocure. Exhibits 1-5 were admitted into evidence without objection. The Record was held open until August 17, 2018 at 5:00 p.m. CST for submission of additional documents including a BCBS policy regarding TTF for non-Medicare

¹ One or more CDs containing audio recordings of the hearings held in this matter are included with the record.

clients, an FDA approval letter and updated medical records for the Enrollee. Upon receipt of the records, they were admitted as Exhibit 6 and the Record was closed.

Issues

The issues before the Administrative Law Judge include all of the issues brought out in the initial determination, coverage determination, or organization determination; redetermination; or reconsideration that were not decided entirely in a party's favor, for the claims or other appealed matters specified in the request for hearing.

Findings of Fact

After careful consideration of the entire record and hearing testimony, this ALJ finds that the following facts were established:

1. The Enrollee, a male, was age 73 when the Optune device was requested. On January 8, 2018, the Enrollee was hospitalized for recurrent falls and unstable gait. (Exh. 4, p. 15.) Computed tomography (CT) and magnetic resonance imaging (MRI) scans showed he had a cerebral lesion. *Id.* On January 9, 2018, the Enrollee underwent a stereotactic biopsy which showed he had a tumor consistent with grade IV glioblastoma multiforme. (Exh. 4, pp. 15-16.)
2. The Enrollee's physician documented that surgery was considered but after discussing it with another doctor, it was not done. (Exh. 4, p. 18.) The Enrollee has a high risk of neurologic complications from the surgery with permanent motor deficits postoperatively. *Id.*
3. The Enrollee completed a course of concurrent radiation therapy and Temodar (temozolomide) on March 14, 2018. (Exh. 4, p. 15.)
4. On March 14, 2018, the Beneficiary's physician, M.D., prescribed an Optune device for the Enrollee for treatment of glioblastoma multiforme. (Exh. 2, pp. 1-2.)
5. On March 16, 2018, Novocure sent an invoice for Optune plus transducers to the Enrollee, who lives in Indiana. (Exh. 1, p. 17.)
6. He began another course of Temodar on April 14, 2018 and was using it in conjunction with Optune tumor treatment field therapy. (Exh. 4, pp. 15, 18.)
7. On July 6, 2018, the Enrollee's physician noted the Enrollee's June MRI showed stable disease but increasing vasogenic edema. The temozolomide dose was reduced due to fatigue and he was going to add Avastin, another chemotherapy drug. (Exh. 4, pp. 23-24.)
8. The Novocure summary states that the NovoTTF-100A device (the precursor to the Optune device) is a portable, wearable medical device that delivers tumor treating fields to a targeted tumor. (Exh. 5, p. 55.) The tumor treating fields inhibit cancer cell replication. (Exh. 5, p. 56.)

9. On April 8, 2011, the Food and Drug Administration (FDA) issued pre-market approval for the NovoTTF-100A system for treatment of adults with histologically-confirmed or radiologically-confirmed glioblastoma multiforme recurrence in the supratentorial region of the brain after receiving chemotherapy, to be used as a monotherapy after surgical and radiation options had been exhausted. (Exh. 5, p. 44.)
10. In 2013, CMS determined the tumor treatment fields device was durable medical equipment. (Exh. 5, p. 43.)
11. The Journal of the American Medical Association published a study of maintenance therapy for newly-diagnosed glioblastoma with tumor-treating fields plus temozolomide versus temozolomide alone on December 15, 2015. (R. Stupp et al, *Maintenance Therapy with Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma: A Randomized Clinical Trial*, 314 Journal of the American Medical Association 2535 (2015)). (Exh. 5, pp. 5-15.) The controlled, randomized trial with 695 patients concluded that progression-free survival and overall survival were greater among the patients receiving both tumor treating fields and temozolomide than for patients receiving only temozolomide. (Exh. 2, pp. 10-11.) Based on the interim analysis of the trial, the study was concluded early. (Exh. 2, p. 9.) The interim analysis showed that adding tumor treatment fields to temozolomide chemotherapy “significantly prolonged progression-free and overall survival.” (Exh. 2, p. 13.) In addition, the tumor treatment field therapy did not cause any increase in systemic toxic effects compared with temozolomide alone. (Exh. 5, p. 11.)
12. On October 15, 2015, the FDA approved use of the Optune tumor treatment field device as a treatment for adult patients with histologically-confirmed glioblastoma multiforme with temozolomide for newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy. (Exh. 6, pp. 2-5.)
13. The National Comprehensive Cancer Network (NCCN) guidelines, version 1.2018, references adjuvant temozolomide plus alternating electric field therapy (Optune) and concurrent radiation and temozolomide as “category 1” treatment for glioblastoma. (Exh. 5, pp. 2-3.)
14. Category 1 treatment indicates that the NCCN recommendation was based on a high level of evidence and there was uniform consensus on the NCCN panel that approved the therapy. (Hearing testimony.)
15. Blue Cross Blue Shield (BCBS) of Michigan has a medical policy for tumor treatment fields therapy for glioblastoma for its non-Medicare plans. (Exh. 6, pp. 6-19.) It found the safety and effectiveness of tumor-treatment fields therapy has been established and it is a useful therapeutic option for patients meeting specific selection criteria. (Exh. 6, p. 8.) The BCBS policy states that Optune is medically necessary for adults with newly-diagnosed glioblastoma when used as an adjunct therapy to standard treatments including surgery and completion of combined radiation and temozolomide. *Id.* It is considered investigational/experimental if used for other indications. *Id.*

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with a reconsideration decision is entitled to a hearing before the Secretary of the Department of Health and Human Services, provided there is a sufficient amount in controversy and a request for hearing is filed within 60 days after the Enrollee receives the reconsideration decision. Act § 1869(b)(1); 42 C.F.R. §§ 405.904(a), 405.1000, 405.1002, 405.1006; 422.562(d), 422.600, 422.602. The authority of the Secretary to conduct such hearings has been delegated to Administrative Law Judges within the Office of Medicare Hearings and Appeals. 70 Fed. Reg. 36386, 36387 (June 23, 2005).

B. Scope of Review

The ALJ appeals process is governed by 42 C.F.R. §§ 405.1000–405.1054; 422.562(d), 422.600, 422.602. The ALJ considers all issues not decided entirely in Enrollee's favor in the initial determination, redetermination and reconsideration decisions. 42 C.F.R. § 405.1032(a). In addition, an ALJ may consider certain new issues if the ALJ notifies all parties about the new issues before the start of the hearing. 42 C.F.R. § 405.1032(b).

C. Standard of Review

The ALJ is a finder-of-fact, who conducts a *de novo* review, and issues a decision based on the administrative record, including the hearing record. 42 C.F.R. § 405.1000(d) (2017). Enrollee must furnish sufficient documentary evidence to support the claim and bears the burden of proving the Medicare claim. See 42 C.F.R. § 424.5(a)(6); *Almy v. Sebelius*, 679 F.3d 297, 305 (4th Cir. 2012).

II. Principles of Law

Under Medicare Part C, a Medicare Advantage Plan must pay for those items and services (other than hospice benefits) that are available under Medicare Parts A and B or only Part B according to the corresponding enrollment in coverage. Act § 1852; 42 C.F.R. §§ 422.100(a), (c)(1). An enrollee may also purchase supplemental benefits. 42 C.F.R. § 422.100(c). A Medicare Advantage Plan must provide plan enrollees with coverage of their entitled benefits by “furnishing those benefits directly or through arrangements, or by paying for the benefits.” 42 C.F.R. § 422.101(a).

Under Medicare Part B, a beneficiary is entitled to have payment made on his behalf for medical and other health services. Act § 1832(a)(1). The Act provides that Medicare pays for the rental or purchase of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (“DMEPOS”) if the equipment is used in the patient's home or in an institution that is used as a home. See, e.g., Act §§ 1832(a)(1), (a)(2)(B), (a)(2)(I), 1834(a)(13), 1861(s)(6); 42 C.F.R. § 410.3. See also Act § 1861(n) (defining “durable medical equipment”).

Notwithstanding any other provision of Title XVIII of the Act, no payment may be made for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury

or to improve the functioning of a malformed body member. Act § 1862(a)(1)(A). All Medicare claims must be supported by sufficient information and documentation. Act § 1833(e).

A Medicare Advantage Plan must comply with: national coverage determinations by the Center for Medicare and Medicaid Services (CMS), Part A and B general coverage guidelines from manuals and instructions (unless they conflict with Part C regulations or instructions), and written coverage decisions of local Medicare contractors with jurisdiction. 42 C.F.R. § 422.101(b). ALJs are not bound by Medicare program guidance, such as program memoranda and manual instructions, but ALJs “will give substantial deference to these policies if they are applicable to a particular case.” 42 C.F.R. § 405.1062(a).

The applicable LCD is LCD L34823, which states, “Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.” CGS Administrators, LLC, Local Coverage Determination L34823: Tumor Treatment Field Therapy (LCD L34823) (Jan. 1, 2017). The LCD also references some general documentation requirements for durable medical equipment (DME) and references a policy article. The policy article explains:

Code E0766 describes devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers.

This code is inclusive of all associated supplies necessary for the effective use of code E0766 including, but not limited to, transducers/surface electrodes, lead wires, adhesive patches, connectors, conductive gel and skin preps.

CGS Administrators, LLC, Policy Article A52711: Tumor Treatment Field Therapy (Article A52711) (Jan. 1, 2017).

When a Contractor drafts an LCD, it must comply with CMS’s guidance set out in the Medicare Program Integrity Manual:

Contractor LCDs shall be based on the strongest evidence available. The extent and quality of supporting evidence is key to defending challenges to LCDs. The initial action in gathering evidence to support LCDs shall always be a search of published scientific literature for any available evidence pertaining to the item or service in question. In order of preference, LCDs should be based on:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
 - General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
 - Scientific data or research studies published in peer-reviewed medical journals;
 - Consensus of expert medical opinion (i.e., recognized authorities in the field);
- or
- Medical opinion derived from consultations with medical associations or other health care experts.

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical

community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

LCDs which challenge the standard of practice in a community and specify that an item or service is never reasonable and necessary shall be based on sufficient evidence to convincingly refute evidence presented in support of coverage.

Less stringent evidence is needed when allowing for individual consideration.

CMS, *Medicare Program Integrity Manual (MPIM) (Internet-Only Publ'n 100-08)* ch. 13, § 13.7.1 (Jan. 2015).

Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
 - Furnished in a setting appropriate to the patient's medical needs and condition;
 - Ordered and furnished by qualified personnel;
 - One that meets, but does not exceed, the patient's medical need; and
 - At least as beneficial as an existing and available medically appropriate alternative.

Id.

The Plan's Evidence of Coverage states that the Plan must cover all services covered by Original Medicare and must follow Original Medicare's coverage rules. (Exh. 1, p. 120.) The Plan requires prior authorization and a prescription or a Certificate of Medical Necessity from the doctor before it covers Durable Medical Equipment (DME). (Exh. 1, p. 129.) Durable Medical Equipment is defined by the plan as certain medical equipment ordered by a doctor for medical reasons, and gives the examples of walkers, wheelchairs, or hospital beds. (Exh. 1, p. 250.) The Plan covers all medically necessary durable medical equipment covered by Original Medicare. (Exh. 1, p. 129.) The Plan does not cover services considered not reasonable and necessary, according to the standards of Original Medicare, and does not cover experimental medical and surgical procedures, equipment or medications. (Exh. 1, p. 161.) Experimental procedures and items are those determined by the Plan and Original Medicare to not be generally accepted by the medical community. *Id.*

Analysis

The Enrollee's request for an ALJ hearing was timely and satisfies jurisdictional requirements. The evidence in this case supports a finding that the Plan must cover the Optune tumor treatment field therapy under the Part C Plan.

The Plan denied coverage of the Optune tumor treatment field therapy because it is bound by the LCD, which states that the tumor treating field therapy will be denied as not reasonable and necessary. Although the LCD sets out a categorical denial of tumor treatment field therapy, it does not cite any research or other information that leads to the Contractor's conclusion that Optune is never medically necessary. Contractor LCDs should be based on the strongest evidence available, including randomized clinical studies. CMS guidance in the Medicare Program Integrity Manual states that LCDs which challenge the standard of practice in a community and specify that an item or service is never reasonable and necessary shall be based on sufficient evidence to **convincingly refute** evidence presented in support of coverage. The LCD addressing tumor treatment field therapy was issued in January 2014 and has not been substantively revised since that time. Research on Optune has continued, however, leading to approval of Optune for treatment of newly diagnosed glioblastoma in December of 2015. Randomized controlled studies have concluded that the use of tumor treatment field therapy in conjunction with temozolomide chemotherapy after a course of concurrent radiation and temozolomide treatment is an effective and safe treatment for glioblastoma. In addition, the therapy is generally accepted in the medical community, as indicated by its inclusion in therapy recommendations from the National Comprehensive Cancer Network (NCCN). Furthermore, BCBS has a policy in effect for its non-Medicare patients that found TTFT to be safe, effective and covered under certain circumstances. (Exh. 6, pp. 8-19.) This ALJ gives the applicable LCD substantial deference, but declines to apply the LCD, finding that the evidence presented by the Appellant outweighs the LCD, which cites no evidence in support of its absolute denial of coverage for the Optune device.

This ALJ finds that the Optune tumor treatment field therapy is medically reasonable and necessary for this Enrollee. The Enrollee is diagnosed with glioblastoma multiforme. He was not a candidate for surgical resection of the tumor because there was a high risk of neurologic complications including permanent motor deficits. He has already completed a concurrent course of radiation therapy with temozolomide. He currently is in a maintenance course of temozolomide, and has used the Optune tumor treatment field therapy along with temozolomide with good result. The treatment plan for the Enrollee is similar to what was approved by the FDA in October 2015 and reported in the study published in December 2015, which showed improved survival rates for individuals using tumor treating fields in conjunction with temozolomide. This ALJ finds that the Optune device plus transistors (E0766) is durable medical equipment that is medically reasonable and necessary for this Enrollee and must be covered by the Medicare Part C Plan.

Conclusions of Law

This decision is **FULLY FAVORABLE** to the Enrollee. The Plan is required to grant prior approval for and cover the Optune tumor treatment field therapy (E0766) under the Enrollee's Part C Plan.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED

Dated: **AUG 17 2018**

A handwritten signature in black ink, appearing to read 'D. Malvin', written over a horizontal line.

Daniel H. Malvin
U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City, Missouri

Appeal of:	OMHA Appeal No.: 1-7905397060
Beneficiary:	Medicare: Part B
Medicare No.:	Before: P. Arthur McAfee Administrative Law Judge

DECISION

After carefully considering the evidence in the record, the Administrative Law Judge (ALJ) enters a **FULLY FAVORABLE** decision for (Beneficiary).

PROCEDURAL HISTORY

The Beneficiary submitted a claim to Medicare for electrical stimulation cancer treatment (E0766) for the dates of service from December 8, 2017, to March 8, 2018. Initially and upon redetermination review, the Medicare Administrative Contractor (Contractor) denied the claim. On September 5, 2018, C2C Innovative Solutions, Inc., a Medicare Qualified Independent Contractor (QIC), denied the claim upon reconsideration review.

On September 26, 2018, the Office of Medicare Hearings and Appeals (OMHA) received the Appellant's timely filed request for hearing. (Exh. 3, p. 1). The jurisdictional requirements for a hearing before OMHA are met.

On November 1, 2018, the undersigned held a telephone hearing in this matter. Present at the hearing was Debra Parrish, attorney for the Beneficiary, and Julie Miles, a registered nurse familiar with the device at issue. All exhibits were incorporated into the record without objection.

ISSUES

All issues for the claims or appealed matter specified in the request for hearing that were brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. Specifically, the issue is whether the electrical stimulation cancer treatment (E0766) at issue meets Medicare coverage criteria.

FINDINGS OF FACT

1. The Beneficiary, , a 69-year-old female on the dates of service at issue, had a clinical history of acute onset generalized weakness. On February 25, 2017, the Beneficiary underwent an MRI which revealed lesions and a possible central nervous system glioma. (Exh. 2, pp. 43-44).
2. Between March 3, 2017, and March 7, 2017, the Beneficiary completed several MRIs and a tumor resection, confirming a diagnosis of glioblastoma. (Exh. 2, pp. 36-42). On March 10, 2017, the Beneficiary met with her physician to discuss treatment. (Exh. 2, pp. 29-32). Radiation and temozolomide were recommended, along with consideration of the Optune device and leading edge Gamma Knife radiosurgery. *Id.*
3. Gamma Knife radiosurgery was performed on April 4, 2017, and the Beneficiary tolerated this procedure well. (Exh. 2, pp. 27-28). She was to return to radiation therapy after discharge. *Id.*
4. The Beneficiary was initially prescribed the Optune device in June 2017. (Exh. 2, p. 23). On October 20, 2017 the prescription for the Optune device was renewed for six additional months. (Exh. 2, pp. 9-11).
5. The NCCN Clinical Practice Guidelines Version 1.2018 for Central Nervous System Cancers, include Tumor Treatment Field Therapy (TTFT) treatment, such as Optune, for recurrent glioblastoma. (Exh. 2, p. 45-47).
6. Per the Journal of the American Medical Association (JAMA), “glioblastoma is the most devastating primary malignancy of the central nervous system in adults.” (Exh. 2, p. 49). Most patients with this diagnosis die within 1 to 2 years, and the 5-year survival rate is reported as 10 percent. (Exh. 2, p. 50). A randomized clinical trial published by JAMA in 2015, analyzed 315 patients with glioblastoma who had completed standard chemoradiation therapy, and found that adding TTFT treatment to maintenance temozolomide chemotherapy significantly prolonged progression-free and overall survival. (Exh. 2, pp. 48-57).
7. In 2014, the Society for NeuroOncology (SNO), released an analysis of the EF-14 trial of NovoTTF-100A, the TTFT device now known as Optune. (Exh. 2, p. 84). This trial found that temozolomide chemotherapy and TTFT provided a clinically and statistically significant improvement in progression-free and overall survival in glioblastoma patients. *Id.* It was suggested that TTFT treatment become the new standard of care against glioblastoma. *Id.*
8. In 2011, the Optune TTFT device was approved by the FDA for treatment of adults with glioblastoma after receiving chemotherapy. (Exh. 2, pp. 86-90). The Centers for Medicare and Medicare Services (CMS) determined in 2013 that this TTFT device fell within the durable medical equipment (DME) Medicare benefit category. (Exh. 2, p. 85). This is the only FDA approved treatment for glioblastoma. (Hearing Testimony).

9. A TTFT study was published by the European Journal of Cancer in 2012. (Exh. 2, pp. 141-161). This TTFT study found no improvement in overall survival compared to chemotherapy, but found toxicity and quality of life favored TTFT. *Id.*
10. Proceedings of the National Academy of Sciences of the United States of America (PNAS) published a TTFT study in 2017. (Exh. 2, pp. 162-175). This study focused on patients with recurrent glioblastoma, and found those in a clinical trial of TTFT had median time to disease progression and overall survival values more than double those of historical control patients. *Id.* No device-related serious adverse events were recorded during this trial. *Id.*
11. A BMC Cancer research article published in 2010 found TTFT was a potentially effective treatment of drug resistant tumors. (Exh. 2, p. 176-182). An earlier BMC research article, published in 2009, found results indicating that combining chemotherapy with TTFT may increase chemotherapeutic efficacy and sensitivity without increasing treatment related toxicity. (Exh. 2, pp. 183-195).
12. Virtually every major commercial payer in the United States covers the Optune system for individuals diagnosed with a glioblastoma. Policies in the record reflect coverage from payers such as Highmark, Aetna, Anthem, Humana, Kaiser, UnitedHealthcare, Cigna, Harvard Pilgrim, Geisinger, HealthPartners, and several Blue Cross plans. (Exh. 1, p. 26-31).
13. After being diagnosed with recurrent glioblastoma, average overall survival is approximately 6 months from the time of recurrence without additional effective treatment.¹ Survival at initial presentation is approximately 10 months, even with aggressive chemotherapy.² (Exh. 1, p. 2).
14. During clinical trials, the interim TTFT results were so compelling that the Data Safety Monitoring Board recommended that patients not receiving TTFT be able to cross over, and deemed it unethical to withhold TTFT from those not receiving it. The FDA agreed, and stopped a brain tumor study early based on these positive results. (Exh. 3, p. 1, Hearing Testimony).
15. Per Hearing Testimony, the Beneficiary initially had a terrible prognosis, and has since well outlived her initial life expectancy. (Hearing Testimony).
16. Ms. Parrish stated that the LCD at issue is currently under reconsideration. (Hearing Testimony).

¹ Rulseh et al. "Long-term survival of patients suffering from glioblastoma multiforme treated with tumor-treating fields." World Journal of Surgical Oncology at 1 (2012).

² *Id.*

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

An individual or an organization who is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (“HHS”) provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. 42 C.F.R. § 405.1014; Social Security Act (“Act”) § 1869(b)(1)(A). In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary unless later reviewed by the Medicare Appeals Council. *Id.*

For requests filed in calendar year 2018, the minimum amount remaining in controversy required for an ALJ hearing is \$160.00 (following application of any co-insurance or deductible). Act § 1869(b)(1)(E); 79 Fed. Reg. 57934 (Sept. 26, 2014); 42 C.F.R. §§ 405.1006(b), 405.1006(d)(1)(ii).

To be considered timely, the request for hearing must be received by OMHA within sixty days after the Appellant receives the QIC’s reconsideration decision. The Appellant is presumed to have received the QIC’s reconsideration five days after the date noted on the first page of the reconsideration unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3).

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in the Appellant’s favor. 42 C.F.R. § 405.1032. However, if evidence presented before or during the hearing causes the ALJ to question a fully favorable decision, he or she will notify the Appellant and will consider it an issue at the hearing. *Id.*

An ALJ may issue a decision on the record on his or her own initiative if the evidence in the hearing record supports a fully favorable finding. 42 C.F.R. §§ 405.1000(g), 1038(a). In addition, if all parties to the hearing waive their right to appear at the hearing, the ALJ may make a decision based on the evidence that is in the record and any new evidence that is admitted by the ALJ. 42 C.F.R. § 405.1000(e).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue. 42 C.F.R. § 405.1000(d) and Section 557 of the Administrative Procedures Act. A *de novo* review requires the ALJ to review and evaluate the evidence without regard to the findings in the prior determinations on the claim and make an independent assessment in reliance upon the evidence and controlling laws. All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Act and applicable implementing regulations, are binding on the ALJ. 42 C.F.R. § 405.1063.

The Appellant has the burden of proving each element of a Medicare claim by a preponderance of the evidence (satisfied through the submission of sufficient evidence in accordance with Medicare rules). *See* Act §§ 1814(a)(1), 1815(b), 1833(e); 42 C.F.R. §§ 424.5(a)(6), 405.1018, 405.1028, 405.1030.

II. Principles of Law

A. Statutes and Regulations

The statutory authority for the Medicare program is found in Title XVIII of the Act. 42 U.S.C. § 1395 *et seq.* The Supplementary Medical Insurance program (Part B of Title XVIII of the Act) provides coverage for a variety of medical services and supplies furnished by physicians, or by others in connection with physicians' services, for outpatient hospital services, and for a number of other specific health-related items and services. *See* Act § 1832; *see also* 42 C.F.R. § 410.10. The Secretary of HHS has authority to promulgate regulations which define or clarify the provisions of the Act. Those regulations are generally found at 42 C.F.R. § 410, and other provisions.

B. Medicare Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than an National Coverage Determination, can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. *See also* 42 C.F.R. § 405.1060. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that establishes criteria for coverage of selected types of medical items and services in the form of manuals and local coverage determinations ("LCDs").

Section 1869(f)(2) of the Act provides that Administrative Law Judges will give substantial deference to LCDs or CMS program guidance when applicable, and if they do not follow the policy they must explain why in their decision. *See also* 42 C.F.R. § 405.1062.

Applicable to the instant appeal is LCD L34823: Tumor Treatment Field Therapy (TTFT) (LCD L34823) (July 2016). For any item to be covered by Medicare, it must be eligible for a defined Medicare benefit category, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The LCD further states that CPT code E0766, tumor treatment field therapy will be denied as not medically reasonable and necessary. LCD L34823.

Historically, in making coverage determinations, CMS has interpreted the terms "reasonable and necessary" to mean that the item or service in question is safe and effective and not experimental. CMS has further determined that the relevant tests for applying these terms are whether the item or service has been proven safe and effective based on authoritative evidence, or alternatively, whether the item or service is generally accepted in the medical community as safe and effective for the condition for which it is used. 54 Fed. Reg. 4304 (Jan. 30, 1989); 60 Fed. Reg. 48417 (Sept. 19, 1995); *see also* 52 Fed. Reg. 15,560 (Apr. 29, 1987). Indeed, CMS has provided guidance in the *Medicare Program Integrity Manual* (CMS Pub. 100-08) (*MPIM*) to assist contractors in developing LCDs to aid in creating relevant tests and guidance. The *MPIM* contemplates that, in

making a determination as to whether an item or service is reasonable and necessary, contractors will analyze whether the item or service is safe and effective, and not experimental or investigational. *MPIM*, ch. 13, § 13.5.1. Contractors shall consider a service reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational; and
- Appropriate, including the duration and frequency that is considered appropriate for the service.

The *MPIM* further instructs contractors to base LCDs on the strongest evidence available at the time the determination is issued. In order of preference, this includes:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and ALJs and the Medicare Appeals Council are not bound by CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. 42 C.F.R. § 405.1062(a).
- General acceptance by the medical community (standards of practice), supported by sound medical evidence based on:
 - Scientific data or research studies published in peer-reviewed medical journals;
 - Consensus of expert medical opinion (i.e., recognized authorities in the field); or
 - Medical opinion derived from consultations with medical associations or other health care experts.

Id. at § 13.7.1.

The Manual further explains:

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

ANALYSIS

The Beneficiary is challenging the denial of coverage for placement of electrical stimulation therapy she received for the dates of service from December 8, 2017, to March 8, 2018. The QIC denied payment because medical documentation did not support the need for the device. There was insufficient documentation to quantify the effects of the device. The currently published

studies did not clearly document the effectiveness of the device. As such, payment was not allowed, as the requirements of the LCD were not met. The undersigned came to a different conclusion.

At issue in this case is whether the documentation submitted established Medicare's coverage and payment requirements for payment under Part B of Title XVIII of the Social Security Act. The QIC and the Medicare Administrative Contractor found that the service was not covered by Medicare based on LCD L34823. The QIC correctly determined that LCD L34823 was in effect at the time the services were rendered and that the Optune device for the treatment of glioblastoma was non-covered by Medicare. The LCD plainly states that tumor treatment field therapy is not medically reasonable and necessary, without further explanation. The Beneficiary argues that no basis exists to deny Medicare coverage of a device that is shown in the peer-reviewed literature to be a safe and effective treatment for glioblastoma, a life-threatening condition. The Optune system was approved as safe and effective by the FDA. This is further supported by multiple peer-reviewed studies.

The applicable provisions in LCDs and Medicare manuals are entitled to substantial deference to the extent that they are consistent with the Act, regulations, and rulings. 42 C.F.R. § 405.1062. To the extent that an ALJ deviates from an LCD that deviation must be explained. Under the circumstances presented in this case, the ALJ finds substantial reason to deviate from this applicable LCD.

The medical literature submitted for review supports that the device is safe and effective for patients like the Beneficiary. The record contains numerous studies regarding the device, which the ALJ reviewed. These studies all support that, at a minimum, TTFT treatment improves quality of life and reduces toxicity in patients. Many of the more favorable studies found statistically significant improvements in progression-free and overall survival rates in patients receiving TTFT for glioblastoma. Additionally, minimal side effects or adverse events were reported in patients receiving this treatment. Studies on newly diagnosed glioblastoma reflected the effectiveness of the treatment on individuals who received the device when newly diagnosed, and those who continued using it during unfortunate recurrences. The results reflected statistically significant improvement in overall survival for patients diagnosed with glioblastoma.

Furthermore, Optune is FDA-approved for recurrent and newly diagnosed glioblastoma brain tumors. Glioblastoma is the most common form of primary brain cancer but is still very rare. The NIH designates glioblastoma as a rare disease, with few treatment options. Virtually every major commercial payer in the United States covers the Optune device for individuals diagnosed with a glioblastoma. Additionally, the NCCN Clinical Practice Guidelines 1.2018 for Central Nervous System Cancers, include Tumor Treatment Field Therapy (TTFT) treatment, like the Optune device, for recurrent glioblastoma. Contrary to the findings of the QIC, this ALJ finds that the published studies in the medical literature clearly document the effectiveness of the Optune device, and the documentation satisfactorily quantified the effects of the device.

Having found reason to deviate from the applicable LCD, it must be determined whether the treatment was reasonable and medically necessary for the Beneficiary. A patient's survival time with glioblastoma at initial presentation is approximately 10 months, even with aggressive chemotherapy. The five-year survival rate is about 10 percent. Without additional effective treatment, the average overall survival is approximately 6 months from the time of recurrence.

Recurrent glioblastoma occurs when the tumor recurs or progresses after initial treatment. Recurrent glioblastoma is an end-stage condition. When glioblastoma recurs, patients are rarely eligible for re-operation. As a result, patients with recurrent glioblastoma face severely limited treatment options.

Much like patients in the studies contained in the record, the Beneficiary's physician prescribed the Optune device when the Beneficiary was newly diagnosed with a glioblastoma. The Beneficiary did experience progression of her disease while using the Optune, such as other patients who participated in studies. The Beneficiary's clinical treatment circumstances mirror those of some studies, given her continued use of the Optune device that was originally prescribed when newly diagnosed. This treatment has also produced positive results, as the Beneficiary has since outlived her life expectancy at diagnosis.

Based on the above, the Optune device provided to the Beneficiary was medically reasonable and necessary. The Beneficiary met all of Medicare's coverage requirements for payment under Part B of Title XVIII of the Social Security Act. The Beneficiary submitted sufficient documentation to meet the documentation requirements of section 1833(e) of the Social Security Act, and the medical literature in the record clearly documented the effectiveness of the device. Therefore, the Beneficiary is entitled to reimbursement from Medicare for the electrical stimulation cancer treatment (E0766) for the dates of service from December 8, 2017, to March 8, 2018.

CONCLUSIONS OF LAW

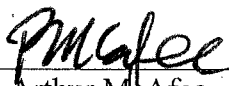
After careful consideration of all the evidence, Medicare Part B coverage is found for the electrical stimulation cancer treatment (E0766) for the dates of service from December 8, 2017, to March 8, 2018. Because this decision is favorable to the Beneficiary, liability will not be addressed.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this Decision.

SO ORDERED

Dated: NOV 06 2018


P. Arthur McAfee
Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Irvine, California

Appeal of:	REDACTED	OMHA Appeal No.: 1-7884243389
Beneficiary:	REDACTED	Medicare: Part B
Medicare No.:	REDACTED	Before: Sean McKee Administrative Law Judge

DECISION

After careful consideration of all the evidence and arguments presented in the record and at the hearing, a **FULLY FAVORABLE** decision is entered for REDACTED hereinafter referred to as the Appellant.

PROCEDURAL HISTORY

This appeal is before the undersigned ALJ following prior adverse determinations made by Noridian Healthcare Solutions (Noridian), the Medicare Administrative Contractor (MAC), and by C2C Innovative Solutions, Inc., the Qualified Independent Contractor (QIC), which denied the Appellant's claim for coverage for tumor treatment field therapy (TTFT or TTF) (E0766) provided on November 22, 2017, December 22, 2017, and January 22, 2018. (Exh. 1, pp. 1-7.)

Following receipt of the QIC's unfavorable reconsideration decision, the Appellant filed a Request for Hearing before an Administrative Law Judge (ALJ), which was received by OMHA on September 17, 2018. (Exh. 3, p. 1.) The Appellant's Request for an ALJ Hearing satisfies the request for hearing requirement specified in Title 42 Code of Federal Regulations (C.F.R.) Section 405.1002(a)(1) because the Appellant's Request for Hearing was filed within 60 days of the QIC's reconsideration decision. (Exhs. 1 & 3.)

On September 19, 2018, a telephonic hearing was held in this matter in Irvine, California. (Hearing CD.) Ms. Debra Parrish, Esq., appeared and argued on behalf of the Appellant. Ms. Julie Miles, R.N., the Clinical Appeals Specialist of NovoCure, also appeared and testified on behalf of the Appellant. The MAC and QIC did not appear at the scheduled hearing. No other parties appeared at the hearing. The undersigned admitted all of the Exhibits into evidence without objection.

ISSUE

Whether the tumor treatment field therapy (TTFT) device, specifically the electrical stimulation center treatment (E0766), provided to the Appellant on November 22, 2017, December 22, 2017, and January 22, 2018 is covered by Medicare.

FINDINGS OF FACT

1. The Appellant, a 73-year-old female, was diagnosed with glioblastoma (i.e. a fast growing brain tumor) in August of 2017. The doctor explained that the Appellant had a left anterior temporal glioblastoma and presented with task confusion and expressive language difficulties. The doctor discussed using radiation, adjuvant Temozolomide (i.e. anti-cancer chemotherapy drug), and TTFT to treat the Appellant's cancerous brain tumor. The Appellant consented to receiving a TTFT device for her therapy. (Exh. 2, p. 4-7, 19-22.)
2. The November 7, 2017 Optune Prescription Form stated that the Appellant was diagnosed with glioblastoma (C71.9) and required NovoTTF treatment. (Exh. 2, p. 7.)
3. Glioblastoma multiforme (GBM) is the most prevalent and most fatal malignant brain tumor in adults accounting for nearly 15% of all brain cancers. However, there is a new noninvasive technology that is intended to treat GBM on an outpatient basis by "exposing cancer cells to alternating electric fields of low intensity and intermediate frequency, cellular polarity, and ionic energy." Specifically, TTFT exposes cancer cells to alternating electric fields, which inhibits tumor growth and causes "cell apoptosis." TTFT has been found to prevent the dividing of tumor cells. (Exh. 3, pp. 1066-1067.)
4. Optune, formerly known as NovoTTF-100A System, has been approved by the United States (U.S.) Food and Drug Administration (FDA) to deliver TTFT therapy. TTFT therapy is delivered by is a portable battery or power supply operated device, which produces alternating electrical fields, called tumor treatment fields ("TTFfields") within the human body. TTFfields are applied to the patient by electrically-insulated surface electrodes. The TTFfields are used to disrupt the rapid cell division exhibited by cancer cells. The NovoTTF-100A System is comprised of two main components: (1) an Electric Field Generator (the NovoTTF-100A device); and (2) INE Insulated Electrodes (the electrodes).¹ (Exh. 3, pp. 667-675, 685, 727, 795.)
5. The Appellant submitted a Review Article entitled "*NovoTTF-100A: a new treatment modality for recurrent glioblastoma*," in support of its position. (Exh. 1, pp. 148-158.) Brain Tumor Center & Neuro-Oncology Unit/Beth Israel Deaconess Medical Center and Harvard Medical School found that NovoTTF-100A is a novel therapy for the treatment of recurrent glioblastoma and has comparable efficacy and less toxicity as compared to conventional drug treatments in the recurrence setting. *Id.* The NovoTTF-100A device interferes with the dividing tumor cells at anaphase². *Id.*
6. The Appellant submitted a Review Article entitled, "*NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma: randomized phase III trial of a novel*

¹ https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034c.pdf

² When replicated chromosomes split and move to opposite poles of the cell.

treatment modality,” in support of its position. (Exh. 1, pp. 137-147.) Thirty (30) physicians from various universities and hospitals across the globe, including Tel Aviv Medical Center, University of Hamburg, and the Cleveland Clinic Foundation performed comprehensive research on the effectiveness and toxicity of conventional chemotherapy versus TTF therapy for patients diagnosed with glioblastoma. As expected, conventional chemotherapy toxicity caused far more gastrointestinal, hematological, and infectious adverse events as compared to TTF therapy. Furthermore, multiple animal experiments showed the “enhanced affect [when] TTF is combined with chemotherapy.” Because of this successful animal trial, the U.S. and Europe have approved this device for the treatment of glioblastoma. *Id.*

7. The Appellant submitted a Review Article entitled, “*Tumor treating fields: Concept, Evidence, and Future,*” in support of its position. (Exh. 1, pp. 193-200.) The Department of Internal Medicine and Tumor Center (Medical Oncology) in Switzerland found that after conducting extensive research, “TTFT inhibits proliferation and allows for cancer cell destruction in vitro and in vivo.” TTFT was found to improve human prognosis in recurrent glioblastomas and there were “no serious adverse events found” related to TTF therapy. In fact, TTFT is “toxicity-free for treated patients except for mild to moderate dermatitis underneath the electrodes. *Id.*”
8. The Appellant submitted a randomized clinical trial entitled, “*Maintenance Therapy with Tumor-Treating Fields plus Temozolomide vs. Temozolomide Alone for Glioblastoma*” in support of its position. (Exh. 1, pp. 50-60.) The clinical trial included 695 patients with newly diagnosed glioblastomas in 83 centers in the United States, Canada, Europe, Israel, and South Korea. This clinical trial found that by adding TTFT with Temozolomide chemotherapy, it “*significantly prolonged progressive-free and overall survival.*” *Id.*
9. The Appellant submitted a Research Article entitled, “*Chemotherapeutic treatment efficacy and sensitivity are increased by adjuvant alternating electric fields (TTFields),*” in support of its position. (Exh. 1, pp. 180-192.) This article stated that TTF or TTFields may be used not only as an effective “stand alone anti-proliferation agent” for cancer cells but also as an effective adjuvant, which “enhances chemotherapy efficacy without an increase in toxicity.” The article stated that these excellent results raise the possibility of dose reduction of chemotherapy only when used in combination with TTFields. The researchers stated that dose reduction is of paramount importance since chemotherapy drug doses are often associated with a high degree of toxicity. *Id.*
10. The Appellant submitted an extensive clinical oncology report entitled, “*Clinical Cancer Advances 2018: Annual Report on Progress against Cancer from the American Society of Clinical Oncology,*” from the Journal of Clinical Oncology, which discussed cancer advances in 2018. This article addressed glioblastoma patients treated with TTFT. Clinical research found that the “risk of death” was reduced by 37% for patients using the TTFT device as compared to patients using chemotherapy alone. Additionally, TTFT was also found to double the 5-year survival rate from 5% to 13%. (Exh. 3, pp. 451-477.)
11. The Appellant submitted a case report entitled, “*Long-term survival of patients suffering from glioblastoma multiforme treated with Tumor-Treating Fields,*” from the World Journal of Surgical Oncology, which discussed case studies of four patients treated with

TTFT. In this case report, two patients with glioblastoma multiforme (GBM) were treated with TTFT and two patients with recurrence glioblastoma multiforme (RGBM) were treated with TTFT. Consequently, after 7 years, the two patients with GBM and the two patients with RGBM were in “good health” and were “no longer receiving any treatment” coupled with “no clinical or radiological evidence of recurrence.” (Exh. 3, pp. 526-531.)

12. The Appellant submitted 51 fully favorable decisions by ALJs addressing TTF therapy. This Exhibit was 424 pages and it included both Part C and Part B appeals. (Exh. 3, pp. 11-435.)
13. The Appellant submitted 16 peer-reviewed articles, which meticulously analyzed the TTFT device provided to *glioblastoma* patients. These articles supported the Appellant’s position for coverage because medical data and research demonstrated that *glioblastoma* patients who were provided TTFT increased their overall survival. This Exhibit was 195 pages. (Exh. 3, pp. 437-632.)
14. According to the FDA website, “the *breakthrough* finding made by NovoCure was that finely tuned alternating fields of very low intensity, now termed TTFields (Tumor Treating Fields) cause a significant slowing in the growth of cancer cells. Due to the unique geometric shape of cancer cells when they are multiplying, TTFields cause the building blocks of these cells to move and pile up in such a way that the cells physically explode. In addition, cancer cells also contain miniature building blocks which act as tiny motors in moving essential parts of the cells from place to place. TTFields cause these tiny motors to fall apart since they have a special type of electric charge. As a result of these two effects, cancer tumor growth is slowed and can even reverse after continuous exposure to TTFields. Other cells in the body (normal healthy tissues) are affected much less than cancer cells since they multiply at a much slower rate if at all. In addition, TTFields can be directed to a certain part of the body, leaving sensitive areas out of their reach. In conclusion, TTFields hold the promise of serving as a brand new cancer treatment with very few side effects and promising affectivity in slowing or *reversing* this disease.”³

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Section 1869(b)(1)(A) of the Act.

In implementing this statutory directive, the Secretary has delegated authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *See* 74 Fed. Reg. 65296 (December 9, 2009). A hearing before an ALJ is

³ https://clinicaltrials.gov/ct2/show/study/NCT00916409?show_desc=Y#desc

available only if the remaining amount in controversy meets the jurisdictional amount. 42 Code of Federal Regulations (C.F.R.) § 422.600(b). A request for hearing is timely if filed within sixty days after receipt of the reconsideration decision. 42 C.F.R. § 422.602(b).

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. However, if evidence presented before the hearing causes the ALJ to question a fully favorable portion of the determination, the ALJ will notify the parties before the hearing and will consider it an issue at the hearing.

C. Standard of Review

An ALJ conducts a de novo review and issues a decision based on the hearing record. 42 C.F.R. § 405.1000(d).

II. Principles of Law

A. Statutes and Regulations

An ALJ is bound by statutes, regulations, national coverage determinations ("NCD"), and Medicare Rulings. (42 C.F.R. §§ 405.4060(a)(4) and 405.1063.) An ALJ is not bound by a local coverage determination ("LCD") or Medicare program guidance such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. (42 C.F.R. § 405.1062(a).) If an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed. (42 C.F.R. § 405.1062(b).)

Section 1862(a)(1)(A) of the Social Security Act ("Act") provides that notwithstanding any other provisions of title XVIII of the Act, items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member are excluded from coverage.

42 C.F. R §405.1062 - Applicability of local coverage determinations and other policies *not binding* on the ALJ or attorney adjudicator and Council provides:

(a) ALJs and attorney adjudicators and the Council are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.

(b) If an ALJ or attorney adjudicator or Council declines to follow a policy in a particular case, the ALJ or attorney adjudicator or Council decision must explain the reasons why the policy was not followed. An ALJ or attorney adjudicator or Council decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.

(c) An ALJ or attorney adjudicator or the Council may not set aside or review the validity of an LMRP or LCD for purposes of a claim appeal. An ALJ or the DAB may review or set aside an LCD (or any part of an LMRP that constitutes an LCD) in accordance with part 426 of this title.

42 C.F.R. §426.300 Review of LCDs, NCDs, and deemed NCDs provides:

(a) Upon the receipt of an acceptable LCD complaint as described in §426.400, an ALJ conducts a review of a challenged provision (or provisions) of an LCD using the reasonableness standard.

(b) Upon the receipt of an acceptable NCD complaint as described in §426.500, the Board conducts an NCD review of a challenged provision (or provisions) of an NCD using the reasonableness standard.

(c) The procedures established in this part governing the review of NCDs also apply in cases in which a deemed NCD is challenged.

42 C.F.R. §426.310 LCD and NCD reviews and individual claim appeals provide:

(a) LCD and NCD reviews are distinct from the claims appeal processes set forth in part 405, subparts G and H; part 417, subpart Q; and part 422, subpart M of this chapter.

(b) An aggrieved party must notify the ALJ or the Board, as appropriate, regarding the submission and disposition of any pending claim or appeal relating to the subject of the aggrieved party's LCD or NCD complaint. This reporting obligation continues through the entire LCD or NCD review process.

42 C.F.R. §426.320 Who may challenge an LCD or NCD.

(a) Only an aggrieved party may initiate a review of an LCD or NCD (including a deemed NCD), or provisions of an LCD or NCD by filing an acceptable complaint.

(b) Neither an ALJ nor the Board recognizes as valid any attempt to assign rights to request review under section 1869(f) of the Act.

B. Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than an National Coverage Determination (NCD), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local medical review policies (LMRPs) or Local Coverage Determinations (LCDs).

ALJs are not bound by LCDs, LMRPs, or CMS program guidance such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.

Noridian's LCD **L34823** – Tumor Treatment Field Therapy (TTFT) (Revision Effective Date Jan. 1, 2017) provides in part:

Coverage Indications, Limitations, and/or Medical Necessity

...

The purpose of a Local Coverage Determination (LCD) is to provide information regarding “reasonable and necessary” criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the “reasonable and necessary” criteria contained in this LCD there are other payment rules, which are discussed in the following documents that must also be met prior to Medicare reimbursement:

For the items addressed in this LCD, the “reasonable and necessary” criteria, based on Social Security Act §1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. (Emphasis added).

...

HCPCS Codes

...

E0766 ELECTRICAL STIMULATION DEVICE USED FOR CANCER TREATMENT, INCLUDES ALL ACCESSORIES, ANY TYPE

...

Noridian's Policy Article A52711- Tumor Treatment Field Therapy (TTFT) (Revision Effective Date Jan. 1, 2017) provides in part:

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. “reasonable and necessary”). Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage

Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Code E0766 is in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories.

Separate billing of supplies and/or accessories will be denied as unbundling. Code A4555 is not valid for billing to Medicare. If code A4555 is billed, it will be denied as an invalid code.

CODING GUIDELINES

Code E0766 describes devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers.

This code is inclusive of all associated supplies necessary for the effective use of code E0766 including, but not limited to, transducers/surface electrodes, lead wires, adhesive patches, connectors, conductive gel and skin preps.

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Central Nervous System Cancers Version 1.2016 provides that alternating electric field therapy for glioblastoma and is a category 2B recommendation.

Noridian's Policy Article **A52711** states in pertinent part:

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For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary"). Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

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This code is inclusive of all associated supplies necessary for the effective use of code E0766 including, but not limited to, transducers/surface electrodes, lead wires, adhesive patches, connectors, conductive gel and skin preps.

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

ANALYSIS

The issue on appeal is whether the Appellant is entitled to coverage for the TTFT device (HCPCS code E0766) provided on November 22, 2017, December 22, 2017, and January 22, 2018 under Medicare Part B. The Appellant's request was made in a timely manner and the claim satisfies the jurisdictional requirement for an ALJ Hearing before OMHA. I conducted a *de novo* review of the evidence to evaluate, without regard to the findings in the prior determinations, and to determine whether the Appellant established the requirements for Medicare coverage.

Medicare makes payment on items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." *See* § 1862(a)(1) of the Act. All Medicare claims for payment must be supported by sufficient information and documentation. *See* § 1833(e) of the Act.

The Appellant's attorney representative, Ms. Debra Parrish, stated that the Appellant was 73-year-old female and she was diagnosed with a glioblastoma in August 2017. From September 2017 through October 2017, the Appellant completed concurrent radiation and chemotherapy treatment. Ms. Parrish stated that the Appellant was prescribed the Optune device to deliver TTFT treatment to her glioblastoma. Ms. Parrish stated that the Contractor denied the claims stating that the device was not reasonable and necessary. She explained that the QIC found that the studies do not document the effectiveness of the device, that the effectiveness of the device was not quantified for this Appellant, and that the LCD requirements were not met. Ms. Parrish argued that the QIC is wrong. She stated that the studies show that the device is effective. Indeed, one trial was suspended because it was so effective. She argued that the evidence is overwhelming on how effective this device is. Ms. Parrish went on to say that the device received a level 1 approval, which means there is unanimous agreement that the device is effective. She further stated that the device was clinically effective for the Appellant as evidenced by the fact that she is still alive today despite the fact that she was only given 10 months to live. Finally, she asserted that the LCD does not apply to patients who have recently been diagnosed with glioblastoma.

Also, Ms. Parrish argued that the LCD is inconsistent with current medical literature and it is not substantiated by the medical community. (Hearing CD.)

Ms. Julie Miles, the Clinical Appeals Specialist of NovoCure, appeared and testified on behalf of the Appellant. Ms. Miles testified that the Appellant had an MRI, which showed a mass in the left temporal lobe. She testified that the surgery showed that the Appellant had a newly diagnosed glioblastoma. She testified that the Appellant's physician recommended chemotherapy, radiation, and the TTFT device. She stated that the Appellant has since had stable MRIs. She asserted that the Appellant's last MRI showed *no progression* of the disease, so the device is working. (Hearing CD.)

The testimony provided by Ms. Miles and the argument provided by Ms. Parrish were trustworthy, credible, persuasive, and supported by the record.

After carefully considering the evidence in the record as well as the arguments and testimony presented at the hearing, I find that the TTFT device was medically reasonable and necessary for the Appellant and shall be covered by Medicare.

First, TTFT has been approved by the Food and Drug Administration (FDA)⁴ since April 2011. According to the FDA website, "the *breakthrough* finding made by NovoCure was that finely tuned alternating fields of very low intensity, now termed TTFields (Tumor Treating Fields), cause a significant slowing in the growth of cancer cells. Due to the unique geometric shape of cancer cells when they are multiplying, TTFields cause the building blocks of these cells to move and pile up in such a way that the cells physically explode. In addition, cancer cells also contain miniature building blocks which act as tiny motors in moving essential parts of the cells from place to place. TTFields cause these tiny motors to fall apart since they have a special type of electric charge. As a result of these two effects, cancer tumor growth is slowed and can even reverse after continuous exposure to TTFields. Other cells in the body (normal healthy tissues) are affected much less than cancer cells since they multiply at a much slower rate if at all. In addition, TTFields can be directed to a certain part of the body, leaving sensitive areas out of their reach. In conclusion, TTFields hold the promise of serving as a brand new cancer treatment with very few side effects and promising affectivity in slowing or reversing this disease."⁵ The FDA asserts that cancer growth is slowed and can be reversed after using this device.

Second, while giving due consideration to the requisite LCD, I find that this LCD cannot be followed in this case for a multitude of reasons. LCD L34823 states in pertinent part, "tumor treatment field therapy (E0766) will be denied as not reasonable and necessary."⁶ Nevertheless, the QIC based its decision on an LCD that does not contain any discussion, rationale, or any explanation for its conclusions. LCD L34823 categorically denies that *any* TTFT treatment is reasonable and necessary under *any* circumstance without setting forth an underlying basis, discussion, criteria, or rationale for that determination. LCD L34823 is noticeably outdated and

⁴The U.S. Food and Drug Administration, in October 2015, approved an expanded indication for the Optune device by NovoCure for TTF (the treatment at issue in this appeal), to treat patients, as the Appellant, with newly-diagnosed GBM. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm465744.htm>.

⁵https://clinicaltrials.gov/ct2/show/study/NCT00916409?show_desc=Y#desc

⁶Noridian Healthcare Solutions, LLC: Local Coverage Determination L34823: Tumor Treatment Field Therapy (TTFT) (LCD 34823)(October 2015).

ignores medically relevant data from the most prestigious medical institutions in the world including medical opinions, research articles, peer-review studies, university research, clinical oncology reports, etc., and it ignores the medical findings of the FDA in the last 7 years. This data and research, which has been ignored clearly supports a finding that TTFT treatment is medically reasonable and necessary for patients like the Appellant. TTFT is not experimental or investigational but has been approved by the FDA. Furthermore, the sparse nature of any medical reasoning in LCD L34823 provides additional reasons not to follow it here, where the medical evidence, testimony, and argument so overwhelmingly support the Appellant's case. Regardless of the guidance provided by LCD L34823, a departure from the guidelines set forth in this LCD is required based upon the Appellant's serious condition, the great benefits realized by the Appellant after using this device, and the vast medical findings and research in the last decade. Furthermore, federal regulations *permit* ALJs to decline to follow a local coverage policy. 42 C.F.R. Sec. 405.1062.

Third, the evidence supports the need for this device pursuant to Section 1862(a)(1) of the Social Security Act. Sufficient information was provided to corroborate the Appellant's contentions pursuant to Section 1833(e) of the Social Security Act. *See* 42 C.F.R. § 424.5(a)(6). The Appellant was suffering from a deadly malignant brain tumor and needed the best treatment, which could be afforded to her. The Appellant suffered from glioblastoma, which is an aggressive form of brain cancer. She was provided extensive treatment since her diagnosis in August 2017. The Appellant underwent surgery, chemotherapy, radiation, and eventually she was prescribed TTF therapy. The Appellant, on the advice of her treating doctor, seeks coverage for the treatment services furnished by NovoCure. The Optune treatment or NovoTTF-100A System was highly recommended by her doctor. This therapy uses alternating electrical fields to interfere with the rapid growth and division of cancer cells. The Appellant provided over 1,000 pages of medical literature in support of its position. The medical literature is overwhelming in establishing the medical reasonableness and necessity for this device for this Appellant. For example, the Brain Tumor Center & Neuro-Oncology Unit of Beth Israel Deaconess Medical Center and Harvard Medical School conducted research and found that NovoTTF-100A has comparable efficacy and less toxicity as compared to conventional drug treatments for glioblastoma multiforme. (Exh. 1, pp. 148-158.) Thirty physicians from universities and hospitals across the globe including Tel Aviv Medical Center, University of Hamburg, and the Cleveland Clinic Foundation, etc., performed comprehensive research on the effectiveness and toxicity of conventional chemotherapy versus TTFT. They found that conventional chemotherapy treatment caused far more gastrointestinal, hematological, and infectious adverse events as compared to TTFT. Furthermore, multiple experiments suggest the enhanced affect when TTF is combined with chemotherapy. (Exh. 1, pp. 137-147.) The Department of Internal Medicine and Tumor Center (Medical Oncology) in Switzerland found that after conducting extensive research, TTFT inhibits proliferation and allows for cancer cell destruction in vitro and in vivo. They found that TTFT improves human prognosis in recurrent glioblastomas and there are "no serious adverse events found" related to TTF therapy. In fact, they argued that TTFT is "toxicity-free" except for mild to moderate dermatitis underneath the electrodes. (Exh. 1, pp. 193-200.) The Appellant submitted a randomized clinical trial in which 695 patients were treated with newly diagnosed glioblastomas in 83 centers in the United States, Canada, Europe, Israel, and South Korea. The results were very remarkable. The clinical trial concluded that adding TTFT with Temozolomide chemotherapy "*significantly* prolonged progressive-free and overall survival." (Exh. 1, pp. 50-60.) The Appellant submitted a Research Article, which found that TTF fields may be used not only as an effective "stand alone anti-proliferation agent" for cancer cells but also as an effective adjuvant enhancing "chemotherapy

efficacy without an increase in toxicity.” This article stated that these excellent results raise the possibility of dose reduction of chemotherapy when used in combination with TTFields. The researchers explained that dose reduction is of paramount importance since chemotherapy drug doses are often associated with a high degree of toxicity. (Exh. 1, pp. 180-192.) The Appellant submitted a clinical oncology report, which discussed cancer advances in 2018. This report discussed glioblastoma patients treated with TTFT and it found that the “risk of death” was reduced by 37% for patients using the TTFT device compared to those who used only chemotherapy. TTFT was also found to double the 5-year survival rate from 5% to 13%. (Exh. 3, pp. 451-477.) The Appellant submitted a case report, which discussed case studies on four specific patients treated with TTFT, two patients with glioblastoma multiforme (GBM) and two patients with recurrence glioblastoma multiforme (RGM). After 7 years these 4 patients were in “good health” and were “no longer receiving any treatment” coupled with “no clinical or radiological evidence of recurrence.” (Exh. 3, pp. 526-531.) Thus, after weighing all the evidence, the medical reasonableness and necessity for using such a device to treat the Appellant’s condition was clearly warranted. Even though the treatment was very expensive, it is comparable to using expensive chemotherapy drugs, which are not as effective as TTFT.

Lastly, the QIC has provided no medical evidence to cast any doubt on the effectiveness of the TTFT treatment, especially as applied to treating this Appellant. In fact, there is no evidence on the contrary in the record. Therefore, for all these reasons, the TTFT device was medically reasonable and necessary and currently the best treatment for the Appellant’s condition and shall be covered pursuant to the provisions of Section 1862(a)(1) of the Social Security Act.

Section 1879 of the Act provides that when Medicare excludes payment and coverage on the basis of §§ 1862(a)(1), 1862(a)(9), 1879(e), or 1879(g) of the Act, payment may nevertheless be made for items or services if neither the beneficiary nor the provider or supplier knew, or could not reasonably be expected to have known, that the items or services would not be covered or payable by Medicare. I have determined that Medicare payment should be allowed on the TTFT device, because it was medically appropriate, reasonable, and necessary for this Appellant. As such, the limitation of liability issue is moot and need not be discussed.

CONCLUSIONS OF LAW

1. The Appellant is entitled to coverage for the TTFT (E0766) provided on November 22, 2017, December 22, 2017, and January 22, 2018. This device was medically necessary pursuant to the FDA research and guidelines, the overwhelming medical data submitted by the Appellant, and pursuant to Section 1862(a)(1) of the Social Security Act.

[The Decision continues on the next page.]

2. The limitation of liability under Section 1879 of the Social Security Act does not apply, as the issue is moot. Medicare payment shall be allowed on the TTFT device.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated: _____

JAN 03 2019


Sean McKee

Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Irvine, California

Appeal of:

OMHA Appeal No.: 1-7737630574

Beneficiary:

Medicare: **Part B**

Medicare No.:

Before: **Sean McKee**
Administrative Law Judge

DECISION

After careful consideration of all the evidence and arguments presented in the record and at the hearing, a **FULLY FAVORABLE** decision is entered for _____, hereinafter referred to as the Appellant.

PROCEDURAL HISTORY

This appeal is before the undersigned ALJ following prior adverse determinations made by Noridian Healthcare Solutions (Noridian), the Medicare Administrative Contractor (MAC), and by C2C Innovative Solutions, Inc., the Qualified Independent Contractor (QIC), which denied the Appellant's claim for coverage for tumor treatment field therapy (TTFT or TTF) (E0766) provided to him from July 28, 2017 through September 28, 2017. (Exh. 1, pp. 1-6.)

Following receipt of the QIC's unfavorable reconsideration decision, the Appellant filed a Request for Hearing before an Administrative Law Judge (ALJ), which was received by OMHA on August 2, 2018. (Exh. 3, p. 1.) The Appellant's Request for an ALJ Hearing satisfies the request for hearing requirement specified in Title 42 Code of Federal Regulations (C.F.R.) Section 405.1002(a)(1) because the Appellant's Request for Hearing was filed within 60 days of the QIC's reconsideration decision. (Exhs. 1 & 3.)

On September 19, 2018, a telephonic hearing was held in this matter in Irvine, California. (Hearing CD.) Ms. Debra Parrish, Esq., appeared and argued on behalf of the Appellant. Mr. Justin Kelly, R.N., the Regional Vice President of NovoCure, also appeared and testified on behalf of the Appellant. No other parties appeared at the hearing. The undersigned admitted all of the Exhibits into evidence without objection.

ISSUE

Whether the tumor treatment field therapy (TTFT) device, specifically the electrical stimulation center treatment (E0766), provided to the Appellant from June 28, 2017 through September 28, 2017 is covered by Medicare.

FINDINGS OF FACT

1. The Appellant, a 79-year-old male, was diagnosed with “aggressive” glioblastoma (i.e. a fast growing brain tumor). The doctor explained that this brain tumor was not curable; however, the goal of treatment was to prolong his life for as long as possible and to maintain a quality of life. The doctor stated that the Appellant would start on chemo-radiation with Temozolomide (TMZ) at 150 mg/m²/d for 1 cycles and then 200 mg/m²/d for 2-12 cycles. The doctor also addressed the “survival advantage” of taking NovoCure-TTF with TMZ during the adjuvant phase. The Appellant consented to receiving NovoCure-TTF for his therapy. (Exh. 2, p. 29.)
2. The April 5, 2017 Optune Prescription Form stated that the Appellant was diagnosed with glioblastoma and required NovoTTF treatment. (Exh. 2, p. 17.)
3. Glioblastoma multiforme (GBM) is the most common and deadly malignant brain tumor in adults, with the median age of diagnosis being 64 years. GBM is the deadliest brain tumor with only a third of patients surviving for 1 year and less than 5% living beyond 5 years. The primary treatment for GBM is to surgically remove as much of the tumor as possible coupled with radiation therapy, chemotherapy, or a combination of the two. However, there is a new noninvasive technology that is intended to treat GBM on an outpatient basis using electrical fields and it is called TTFT. Specifically, TTFT exposes cancer cells to alternating electric fields of low intensity and intermediate frequencies, which inhibit tumor growth and reduce tumor angiogenesis. TTFT has been found to prevent the dividing of tumor cells. (Exh. 3, p. 1233.)
4. Optune, formerly known as NovoTTF-100A System, has been approved by the United States (U.S.) Food and Drug Administration (FDA) to deliver TTFT therapy. TTFT therapy is delivered by battery-powered device that generates electrical fields using disposable electrodes that are noninvasively attached to the patient’s shaved scalp over the site of the tumor. This device is used on a continuous basis (20-24 hours per day) throughout the duration of treatment, which can last for several months. (Exh. 3, p. 1234.)
5. The Appellant submitted a Review Article entitled “*NovoTTF-100A: a new treatment modality for recurrent glioblastoma*,” in support of its position. (Exh. 1, pp. 136-160.) Brain Tumor Center & Neuro-Oncology Unit/Beth Israel Deaconess Medical Center and Harvard Medical School, conducted this research and found that NovoTTF-100A is a novel therapy for the treatment of recurrent glioblastoma and has comparable efficacy and less toxicity as compared to conventional drug treatments in the recurrence setting. *Id.* The NovoTTF-100A device interferes with the dividing tumor cells at anaphase¹. *Id.*

¹ When replicated chromosomes split and move to opposite poles of the cell.

6. The Appellant submitted a Review Article entitled, "*NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma: randomized phase III trial of a novel treatment modality*," in support of its position. (Exh. 1, pp. 125-135.) Thirty (30) physicians from various universities and hospitals across the globe, including Tel Aviv Medical Center, University of Hamburg, and the Cleveland Clinic Foundation, performed comprehensive research on the effectiveness and toxicity of conventional chemotherapy versus TTFT for patients diagnosed with glioblastoma. As expected, conventional chemotherapy toxicity cause far more gastrointestinal, hematological, and infectious adverse events as compared to TTFT. Furthermore, multiple animal experiments also showed the "enhanced affect [when] TTF is combined with chemotherapy." Because of this successful animal trial, the U.S. and Europe have approved this device for the treatment of recurrent glioblastoma. *Id.*
7. The Appellant submitted a Review Article entitled, "*Tumor treating fields: Concept, Evidence, and Future*," in support of its position. (Exh. 1, pp. 181-188.) The Department of Internal Medicine and Tumor Center (Medical Oncology) in Switzerland found that after conducting extensive research, TTFT inhibits proliferation and allows for cancer cell destruction in vitro and in vivo. TTFT was found to improve human prognosis in recurrent glioblastomas and "no serious adverse events found" related to TTF therapy. In fact, TTFT is "toxicity-free from treated patients" except for mild to moderate dermatitis underneath the electrodes. *Id.*
8. The Appellant submitted a randomized clinical trial entitled, "*Maintenance Therapy with Tumor-Treating Fields plus Temozolomide vs. Temozolomide Alone for Glioblastoma*" in support of its position. (Exh. 1, pp. 192-201.) The clinical trial included 695 patients with newly diagnosed glioblastomas in 83 centers in the United States, Canada, Europe, Israel, and South Korea. The results found that by adding TTFT with Temozolomide chemotherapy it "*significantly prolonged progressive-free and overall survival.*" *Id.*
9. The Appellant submitted a Research Article entitled, "*Chemotherapeutic treatment efficacy and sensitivity are increased by adjuvant alternating electric fields (TTFields)*," in support of its position. (Exh. 1, pp. 202-214.) This article stated that TTF or TTFields may be used not only as an effective "stand alone anti-proliferation agent" for cancer cells but also as an effective adjuvant, which "enhances chemotherapy efficacy without an increase in toxicity." The article stated that these excellent results raise the possibility of dose reduction of chemotherapy only when used in combination with TTFields. The researchers stated that dose reduction is of paramount importance since chemotherapy drug doses are often associated with a high degree of toxicity. *Id.*
10. The Appellant submitted an extensive clinical oncology report entitled, "*Clinical Cancer Advances 2018: Annual Report on Progress Against Cancer from the American Society of Clinical Oncology*," from the Journal of Clinical Oncology, which discussed cancer advances in 2018. Specifically, this article addressed glioblastoma patients treated with TTFT. Clinical research found that the "risk of death" was reduced by 37% for patients using the TTFT device compared to those who used chemotherapy alone. Additionally, TTFT was also found to double the 5-year survival rate from 5% to 13%. (Exh. 3, pp. 461.)

11. The Appellant submitted a case report entitled, “*Long-term survival of patients suffering from glioblastoma multiforme treated with Tumor-Treating Fields*,” from the World Journal of Surgical Oncology, which discussed case studies of four patients treated with TTFT. In this case report, two patients with glioblastoma multiforme (GBM) were treated with TTFT and two patients with recurrence glioblastoma multiforme (RGBM) were treated with TTFT. Consequently, after seven (7) years the two patients with GBM and the two patients with RGBM were in “good health” and were “no longer receiving any treatment” coupled with “no clinical or radiological evidence of recurrence.” (Exh. 3, pp. 492-497.)
12. The Appellant submitted 51 fully favorable decisions by ALJs addressing TTF therapy. This Exhibit was 424 pages and it included both Part C and Part B appeals. (Exh. 3, pp. 9-433.)
13. The Appellant submitted 16 peer-reviewed articles, which meticulously analyzed the TTFT device provided to *glioblastoma* patients. These articles supported the Appellant’s position for coverage because medical data and research demonstrated that *glioblastoma* patients who were provided TTFT increased their overall survival. This Exhibit was 195 pages. (Exh. 3, pp. 435-630.)
14. The United States (U.S.) Food and Drug Administration (FDA) has approved NovoTTF-100A device (TTFields, TTF, or TTFT) in April 2011. The NovoTTF-100A device is for the treatment of adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme, following histologically or radiologically-confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy and as an alternative to standard medical therapy for glioblastoma multiforme after surgical and radiation options have been exhausted. (Exh. 1, pg. 97.)
15. According to the FDA website, “the *breakthrough* finding made by NovoCure was that finely tuned alternating fields of very low intensity, now termed TTFields (Tumor Treating Fields) cause a significant slowing in the growth of cancer cells. Due to the unique geometric shape of cancer cells when they are multiplying, TTFields cause the building blocks of these cells to move and pile up in such a way that the cells physically explode. In addition, cancer cells also contain miniature building blocks which act as tiny motors in moving essential parts of the cells from place to place. TTFields cause these tiny motors to fall apart since they have a special type of electric charge. As a result of these two effects, cancer tumor growth is slowed and can even reverse after continuous exposure to TTFields. Other cells in the body (normal healthy tissues) are affected much less than cancer cells since they multiply at a much slower rate if at all. In addition, TTFields can be directed to a certain part of the body, leaving sensitive areas out of their reach. In conclusion, TTFields hold the promise of serving as a brand new cancer treatment with very few side effects and promising affectivity in slowing or *reversing* this disease.”²

² https://clinicaltrials.gov/ct2/show/study/NCT00916409?show_desc=Y#desc

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Section 1869(b)(1)(A) of the Act.

In implementing this statutory directive, the Secretary has delegated authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *See* 74 Fed. Reg. 65296 (December 9, 2009). A hearing before an ALJ is available only if the remaining amount in controversy meets the jurisdictional amount. 42 Code of Federal Regulations (C.F.R.) § 422.600(b). A request for hearing is timely if filed within sixty days after receipt of the reconsideration decision. 42 C.F.R. § 422.602(b).

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. However, if evidence presented before the hearing causes the ALJ to question a fully favorable portion of the determination, the ALJ will notify the parties before the hearing and will consider it an issue at the hearing.

C. Standard of Review

An ALJ conducts a de novo review and issues a decision based on the hearing record. 42 C.F.R. § 405.1000(d).

II. Principles of Law

A. Statutes and Regulations

An ALJ is bound by statutes, regulations, national coverage determinations ("NCD"), and Medicare Rulings. (42 C.F.R. §§ 405.4060(a)(4) and 405.1063.) An ALJ is not bound by a local coverage determination ("LCD") or Medicare program guidance such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. (42 C.F.R. § 405.1062(a).) If an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed. (42 C.F.R. § 405.1062(b).)

Section 1862(a)(1)(A) of the Social Security Act ("Act") provides that notwithstanding any other provisions of title XVIII of the Act, items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member are excluded from coverage.

42 C.F. R §405.1062 - Applicability of local coverage determinations and other policies *not binding* on the ALJ or attorney adjudicator and Council provides:

(a) ALJs and attorney adjudicators and the Council are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.

(b) If an ALJ or attorney adjudicator or Council declines to follow a policy in a particular case, the ALJ or attorney adjudicator or Council decision must explain the reasons why the policy was not followed. An ALJ or attorney adjudicator or Council decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.

(c) An ALJ or attorney adjudicator or the Council may not set aside or review the validity of an LMRP or LCD for purposes of a claim appeal. An ALJ or the DAB may review or set aside an LCD (or any part of an LMRP that constitutes an LCD) in accordance with part 426 of this title.

42 C.F.R. §426.300 Review of LCDs, NCDs, and deemed NCDs provides:

(a) Upon the receipt of an acceptable LCD complaint as described in §426.400, an ALJ conducts a review of a challenged provision (or provisions) of an LCD using the reasonableness standard.

(b) Upon the receipt of an acceptable NCD complaint as described in §426.500, the Board conducts an NCD review of a challenged provision (or provisions) of an NCD using the reasonableness standard.

(c) The procedures established in this part governing the review of NCDs also apply in cases in which a deemed NCD is challenged.

42 C.F.R §426.310 LCD and NCD reviews and individual claim appeals provide:

(a) LCD and NCD reviews are distinct from the claims appeal processes set forth in part 405, subparts G and H; part 417, subpart Q; and part 422, subpart M of this chapter.

(b) An aggrieved party must notify the ALJ or the Board, as appropriate, regarding the submission and disposition of any pending claim or appeal relating to the subject of the aggrieved party's LCD or NCD complaint. This reporting obligation continues through the entire LCD or NCD review process.

42 C.F.R. §426.320 Who may challenge an LCD or NCD.

(a) Only an aggrieved party may initiate a review of an LCD or NCD (including a deemed NCD), or provisions of an LCD or NCD by filing an acceptable complaint.

(b) Neither an ALJ nor the Board recognizes as valid any attempt to assign rights to request review under section 1869(f) of the Act.

B. Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than an National Coverage Determination (NCD), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local medical review policies (LMRPs) or Local Coverage Determinations (LCDs).

ALJs are not bound by LCDs, LMRPs, or CMS program guidance such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.

Noridian's LCD **L34823** – Tumor Treatment Field Therapy (TTFT) (Revision Effective Date Jan. 1, 2017) provides in part:

Coverage Indications, Limitations, and/or Medical Necessity

...

The purpose of a Local Coverage Determination (LCD) is to provide information regarding “reasonable and necessary” criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the “reasonable and necessary” criteria contained in this LCD there are other payment rules, which are discussed in the following documents that must also be met prior to Medicare reimbursement:

For the items addressed in this LCD, the “reasonable and necessary” criteria, based on Social Security Act §1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. (Emphasis added).

...

HCPCS Codes

...

E0766 ELECTRICAL STIMULATION DEVICE USED FOR CANCER TREATMENT, INCLUDES ALL ACCESSORIES, ANY TYPE

...

Noridian's Policy Article A52711- Tumor Treatment Field Therapy (TTFT) (Revision Effective Date Jan. 1, 2017) provides in part:

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary"). Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Code E0766 is in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories.

Separate billing of supplies and/or accessories will be denied as unbundling. Code A4555 is not valid for billing to Medicare. If code A4555 is billed, it will be denied as an invalid code.

CODING GUIDELINES

Code E0766 describes devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers.

This code is inclusive of all associated supplies necessary for the effective use of code E0766 including, but not limited to, transducers/surface electrodes, lead wires, adhesive patches, connectors, conductive gel and skin preps.

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Central Nervous System Cancers Version 1.2016 provides that alternating electric field therapy for glioblastoma and is a category 2B recommendation.

Noridian's Policy Article **A52711** states in pertinent part:

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or

treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. “reasonable and necessary”). Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary’s equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

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Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

ANALYSIS

The issue on appeal is whether the Appellant is entitled to coverage for the TTFT device (HCPCS code E0766) provided from July 28, 2017 through September 28, 2017 under Medicare Part B. The Appellant’s request was made in a timely manner and the claim satisfies the jurisdictional requirement for an ALJ Hearing before OMHA. I conducted a *de novo* review of the evidence to evaluate, without regard to the findings in the prior determinations, and to determine whether the Appellant established the requirements for Medicare coverage.

On January 4, 2016, the Medicare Appeals Council (Council) issued a decision examining whether the Part C Plan should cover a TTFT device for an enrollee. (Docket Number M-15-1354.) The Council asserted that because the enrollee was a member of a Medicare Advantage Plan, Medicare rules and coverage determinations guide whether an item or device is covered. (Page 9.) The Council stated that since Medicare does not cover TTFT based upon the current LCD, the TTFT

device is not reasonable and necessary. The Council further stated that the Plan does not specifically provide supplemental coverage for the device. Thus, the device was not covered. (*Id.*)

On March 1, 2018, the Council issued a decision examining whether another Part C Plan should cover a TTFT device for an enrollee. (Docket Number M-17-6134.) For this appeal, the Council asserted that specifically for MA plans, no legal rationale or individual analysis of the medical record should be applied to depart from the clear provisions of an applicable LCD in the context of a MA plan's coverage determination. (Pages 4-6.) Moreover, the Council explained that while ALJ's and the Council are required to give substantial deference to LCDs under original Medicare, the regulation is clear that LCDs, among other authorities, are binding on MA Plans pursuant to 42 C.F.R. Section 422.101(b). The Council asserted that because an LCD is binding on MA Plans, the Council considers LCDs to be binding on ALJs in Medicare Part C cases. Therefore, the Council found that the TTFT device is neither covered under Medicare nor the Plan's supplemental benefits and the ALJ's decision was reversed. *Id.*

The Appellant's attorney, Ms. Debra Parrish, stated that the QIC denied coverage for insufficient documentation, the ineffectiveness of TTF therapy, and the unknown cost of the device. Ms. Parrish asserted that the Appellant was a 79-year-old male who was diagnosed with glioblastoma. She stated that the physician prescribed surgery, chemotherapy, radiation, and this TTFT device for cancer treatment. She noted that this device makes electrical fields, which frustrate cancer cells by causing them not to divide properly, which slows down the growth of tumors. She asserted that this Appellant was diagnosed with glioblastoma in January 2017 and his life expectancy was only "10 months." However, she pointed out that he is still alive today, which she asserts shows that the device *is* effective. Ms. Parrish stated that there are multiple peer-review studies and medical trials showing this effectiveness; in fact, some studies were terminated early because it was unethical to hold treatment for individuals who were not in the treatment group. Ms. Parrish argued that the LCD was not intended to apply to newly diagnosed glioblastoma patients. She asserted that the consensus of the experts is that the device is effective and should be covered. The device is widely used throughout the country and it is covered by most payers. (Hearing CD.)

Mr. Justin Kelly, the Regional Vice President of NovoCure, appeared and testified on behalf of the Appellant. He testified that the Beneficiary presented to the hospital after several days of left sided weakness and facial droop. He testified that a MRI showed a left frontal mass. He stated that the tumor was removed and it was confirmed to be glioblastoma. Afterwards, he testified that the Appellant began chemotherapy and radiation treatment. Mr. Kelly testified that an MRI was performed in June of 2018, which revealed the Appellant was tolerating the treatment well and that the device was effective. He testified that the provider has 835 centers throughout the United States. He testified that the provider has treated over 7,000 patients and the device is used in every state. He further testified that every insurance company covers this device and all of the major payers cover this device due to its effectiveness. Mr. Kelly explained that the device delivers an electric field/charge to the cells, which inhibits the growth and division of cancer cells. In fact, the cells cannot divide correctly so they die. (Hearing CD.)

The testimony provided by Mr. Kelly and the argument provided by Ms. Parrish were trustworthy, credible, persuasive, and supported by the record.

After carefully considering the evidence in the record as well as the arguments and testimony presented at the hearing, I find that the TTFT device was medically reasonable and necessary for the Appellant and shall be covered by Medicare.

First, TTFT has been approved by the Food and Drug Administration (FDA)³ since April 2011. According to the FDA website, “the *breakthrough* finding made by NovoCure was that finely tuned alternating fields of very low intensity, now termed TTFields (Tumor Treating Fields), cause a significant slowing in the growth of cancer cells. Due to the unique geometric shape of cancer cells when they are multiplying, TTFields cause the building blocks of these cells to move and pile up in such a way that the cells physically explode. In addition, cancer cells also contain miniature building blocks which act as tiny motors in moving essential parts of the cells from place to place. TTFields cause these tiny motors to fall apart since they have a special type of electric charge. As a result of these two effects, cancer tumor growth is slowed and can even reverse after continuous exposure to TTFields. Other cells in the body (normal healthy tissues) are affected much less than cancer cells since they multiply at a much slower rate if at all. In addition, TTFields can be directed to a certain part of the body, leaving sensitive areas out of their reach. In conclusion, TTFields hold the promise of serving as a brand new cancer treatment with very few side effects and promising affectivity in slowing or reversing this disease.”⁴ The FDA asserts that cancer growth is slowed and can be reversed after using this device.

Second, while giving due consideration to the requisite LCD, I find that this LCD cannot be followed in this case for a multitude of reasons. LCD L34823 states in pertinent part, “tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.”⁵ Nevertheless, the QIC based its decision on an LCD that does not contain any discussion, rationale, or any explanation for its conclusions. LCD L34823 categorically denies that *any* TTFT treatment is reasonable and necessary under *any* circumstance without setting forth an underlying basis, discussion, criteria, or rationale for that determination. LCD L34823 is noticeably outdated and ignores medically relevant data from the most prestigious medical institutions in the world including medical opinions, research articles, peer-review studies and university research, clinical oncology reports, etc., and it ignores the medical findings of the FDA in the past 7 years. This data and research, which has been ignored clearly supports a finding that TTFT treatment is medically reasonable and necessary for patients like the Appellant. TTFT is not experimental or investigational but has been approved by the FDA for many years. Furthermore, the sparse nature of any medical reasoning in LCD L34823 provides additional reasons not to follow it here, where the medical evidence, testimony, and argument so overwhelmingly supports the Appellant’s case. Regardless of the guidance provided by LCD L34823, a departure from the guidelines set forth in this LCD is required based upon the Appellant’s serious condition, the great benefits realized by the Appellant after using this device, and the vast medical findings in the last decade. Furthermore, federal regulations permit ALJs to decline to follow a local coverage policy. 42 C.F.R. Sec. 405.1062.

³The U.S. Food and Drug Administration, in October 2015, approved an expanded indication for the Optune device by NovoCure for TTF (the treatment at issue in this appeal), to treat patients, as the Appellant, with newly-diagnosed GBM. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm465744.htm>.

⁴https://clinicaltrials.gov/ct2/show/study/NCT00916409?show_desc=Y#desc

⁵ Noridian Healthcare Solutions, LLC: Local Coverage Determination L34823: Tumor Treatment Field Therapy (TTFT) (LCD 34823)(October 2015).

Third, the evidence supports the need for this device pursuant to Section 1862(a)(1) of the Social Security Act. Sufficient information was provided to corroborate the Appellant's contentions pursuant to Section 1833(e) of the Social Security Act. *See* 42 C.F.R. § 424.5(a)(6). The Appellant was suffering from a deadly malignant brain tumor and needed the best treatment, which could be afforded to him. The Appellant suffered from glioblastoma multiforme, which is an aggressive form of brain cancer. He was provided extensive treatment since his diagnosis in 2017. The Appellant underwent surgery, chemotherapy, radiation, and eventually he was prescribed TTF therapy. The Appellant, on the advice of his treating doctor, seeks coverage for the treatment services furnished by NovoCure. The Optune treatment or Novo-TTF 100A Plus Transducer device was highly recommended by his doctor. (Exh. 1, pp. 26-36 & Hearing CD.) This therapy uses alternating electrical fields to interfere with the rapid growth and division of cancer cells. The Appellant provided approximately 1,500 pages of medical literature in support of its position. The medical literature is overwhelming in establishing the medical reasonableness and necessity for this device for this Appellant. For example, the Brain Tumor Center & Neuro-Oncology Unit of Beth Israel Deaconess Medical Center and Harvard Medical School conducted research and found that NovoTTF-100A has comparable efficacy and less toxicity as compared to conventional drug treatments for glioblastoma multiforme. (Exh. 1, pp. 136-160.) Thirty physicians from universities and hospitals across the globe including Tel Aviv Medical Center, University of Hamburg, and the Cleveland Clinic Foundation, etc., performed comprehensive research on the effectiveness and toxicity of conventional chemotherapy versus TTFT. They found that conventional chemotherapy treatment caused far more gastrointestinal, hematological, and infectious adverse events as compared to TTFT. Furthermore, multiple experiments suggest the enhanced affect when TTF is combined with chemotherapy. (Exh. 1, pp. 125-135.) The Department of Internal Medicine and Tumor Center (Medical Oncology) in Switzerland found that after conducting extensive research, TTFT inhibits proliferation and allows for cancer cell destruction in vitro and in vivo. They found that TTFT improves human prognosis in recurrent glioblastomas and there are "no serious adverse events found" related to TTF therapy. In fact, they argued that TTFT is "toxicity-free" except for mild to moderate dermatitis underneath the electrodes. (Exh. 1, pp. 181-188.) The Appellant submitted a randomized clinical trial in which 695 patients were treated with newly diagnosed glioblastomas in 83 centers in the United States, Canada, Europe, Israel, and South Korea. The results were very remarkable. The clinical trial concluded that adding TTFT with Temozolomide chemotherapy "*significantly* prolonged progressive-free and overall survival." (Exh. 1, pp. 192-201.) The Appellant submitted a Research Article, which found that TTFields may be used not only as an effective "stand alone anti-proliferation agent" for cancer cells but also as an effective adjuvant enhancing "chemotherapy efficacy without an increase in toxicity." This article stated that these excellent results raise the possibility of dose reduction of chemotherapy when used in combination with TTFields. The researchers explained that dose reduction is of paramount importance since chemotherapy drug doses are often associated with a high degree of toxicity. (Exh. 1, pp. 202-214.) The Appellant submitted a clinical oncology report, which discussed cancer advances in 2018. This report discussed glioblastoma patients treated with TTFT and it found that the "risk of death" was reduced by 37% for patients using the TTFT device compared to those who used only chemotherapy. TTFT was also found to double the 5-year survival rate from 5% to 13%. (Exh. 3, pp. 461.) The Appellant submitted a case report, which discussed case studies on four specific patients treated with TTFT, two patients with glioblastoma multiforme (GBM) and two patients with recurrence glioblastoma multiforme (RGBM). After 7 years these 4 patients were in "good health" and were "no longer receiving any treatment" coupled with "no clinical or radiological evidence of recurrence." (Exh. 3, pp. 492-497.) Thus, after weighing all the evidence, the medical reasonableness and necessity for using such a device to treat the Appellant's condition

was clearly warranted. Even though the treatment was very expensive, it is comparable to using expensive chemotherapy drugs, which are not as effective as TTFT.

Fourth, even though the Council reversed two fully favorable Part C decisions decided by ALJs, this is not a Part C case. The Council asserted that LCDs are binding on ALJs in Medicare Part C cases. Section 1871(a)(2) of the Act states that specifically that no rule, requirement, or statement of policy, other than a national coverage determination, can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. CMS and Medicare-contracted carriers only issue guidance and policy statements describing the criteria for coverage of selected types of medical services and supplies. These policies are not binding on an ALJ in adjudicating a claim. Regulations such as an LCD do require that the policies be afforded "substantial deference" and that any departure from these policies be explained in the resulting decision. 42 C.F.R. § 405.1062. The two fully favorable Part C decisions reversed by the Council can be distinguished from this appeal because this appeal is a Part B appeal and not a Part C appeal. Consequently, since this is a Part B appeal, I am not bound by any LCD or any Medicare program guidance concerning TTF therapy.

Lastly, the QIC has provided no medical evidence to cast any doubt about the effectiveness of the TTFT treatment, especially as applied to treating this Appellant. In fact, there is no evidence on the contrary in the record. Therefore, the TTFT device was medically reasonable and necessary and currently the best treatment for the Appellant's condition and shall be covered pursuant to the provisions of Section 1862(a)(1) of the Social Security Act.

Section 1879 of the Act provides that when Medicare excludes payment and coverage on the basis of §§ 1862(a)(1), 1862(a)(9), 1879(e), or 1879(g) of the Act, payment may nevertheless be made for items or services if neither the beneficiary nor the provider or supplier knew, or could not reasonably be expected to have known, that the items or services would not be covered or payable by Medicare. I have determined that Medicare payment should be allowed on the TTFT device, because it was medically appropriate, reasonable, and necessary for this Appellant. As such, the limitation of liability issue is moot and need not be discussed.

CONCLUSIONS OF LAW

1. The Appellant is entitled to coverage for the TTFT (E0766) provided from July 28, 2017 through September 28, 2017. This device was medically necessary pursuant to the FDA research and guidelines, the overwhelming medical data submitted by the Appellant, and pursuant to Section 1862(a)(1) of the Social Security Act.

[The Decision continues on the next page.]

2. The limitation of liability under Section 1879 of the Social Security Act does not apply, as the issue is moot. Medicare payment shall be allowed on the TTFT device.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

NOV 15 2018

Dated: _____



Sean McKee
Administrative Law Judge



**Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND
APPEALS**

**Arlington Field Office
Arlington, Virginia**

Appellant:

ALJ Appeal No.: **1-7708321227**

Enrollee:

Medicare Part: **C**

HICN: *******6196A**

Before: **James Myles
U.S. Admin. Law Judge**

DECISION

After carefully considering the evidence in the record and arguments presented in the hearing, a **FAVORABLE** decision is entered for (Appellant/Enrollee).

PROCEDURAL HISTORY

Appellant is enrolled in the Cariten Health Plan, Inc., a Medicare Advantage Plan administered by Humana (hereinafter "Humana" or the "Plan"). Appellant submitted a claim to the Plan for pre-approval of an electrical stimulation device used for cancer treatment (HCPCS E0766) to be provided by the Provider, Novocure, Inc. (also known as Optune). On May 27, 2018, Humana's Medical Doctor denied the request because the information submitted failed to meet medical necessity criteria of Local Coverage Determination (LCD) L34823 for Tumor Treatment Field Therapy ("TTFT"). (Exh. 1 at 6).

Appellant requested reconsideration from Maximus Federal Services (MAXIMUS), a Medicare Qualified Contractor (the "QIC"). In an unfavorable decision dated May 18, 2018 the QIC denied coverage on the basis that the medical records did not meet the requirements of Local Coverage Determination (LCD) L34823. (Exh. 2 at 3).

Appellant timely requested a hearing before an Administrative Law Judge to review MAXIMUS' denial of Medicare Part C benefits. (Exh. 3). The amount in controversy meets the jurisdictional amount; therefore, there is jurisdiction to hear this case.

An Administrative Law Judge ("ALJ") hearing was conducted by telephone conference before ALJ James Myles on August 28, 2018. At the hearing, the beneficiary's interest was represented by Novocure, the Provider, which was in turn represented by Stephen Hales, Esq. Also appearing for the Provider were Dan McCoy, and Julie Miles (Clinical Specialist). Humana was notified of the hearing date and time in writing with adequate notice. Humana did not respond to the notice of hearing. Prior to the hearing, Humana was contacted by OMHA regarding the hearing both by telephone and e-mail, but still did not appear at the hearing. The telephone hearing was conducted without Humana and the record was left open in the event Humana could demonstrate good cause for failure to appear and wished to have a supplemental hearing. After the hearing held on August 28, 2018 an Order to Show Cause for failure to appear was mailed to Humana. Humana did not respond to the Show Cause within 10 days as required. The record is now closed. Exhibits 1-5 were admitted in the record.

ISSUE

Whether Cariten Health Plan, Inc. (Humana) is required to cover an electrical stimulation device used for cancer treatment (HCPCS E0766) provided by the Appellant/Provider Novocure, Inc. to the Enrollee/Beneficiary?

FINDINGS OF FACT

1. The beneficiary is a 72 year-old male who has the unfortunate diagnosis of glioblastoma. (Exh. 2 at 7). The beneficiary had his mass, which was located in the right parietal lobe, reduced in October of 2016. (*Id.*)
2. The beneficiary's physician recommends continued TTFT to manage his glioblastoma. (*Id.*)
3. The Plan denied coverage based on LCD L34823, released in October 2015, which LCD states that TTFT (E0766) will be denied as not reasonable and necessary. (Exh. 1 at 3).
4. Humana released an updated Medicare Coverage Policy on February 22, 2018. (Exh. 5). This policy states that TTFT will be covered in circumstances where:

Absence of any contraindication listed in the Coverage Limitations section; AND

22 years of age or older; AND

Combined ETTF and temozolomide in individuals with histologically-confirmed newly diagnosed GBM limited to the supratentorial region following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy; OR

Monotherapy for individuals diagnosed with histologically- or radiologically - confirmed recurrent GBM limited to the supratentorial region following treatment with chemotherapy after surgical and radiation treatments have been exhausted.

The contraindications states in the new Humana Medicare Policy include:

- Active implanted medical device (eg, deep brain stimulators, spinal cord stimulators, pacemakers, defibrillators); OR
- Bullet fragments; OR
- Pregnancy; OR
- Shunts; OR
- Skull defects (eg, missing bone with no replacement); OR
- Treatment of other malignant tumors (eg, breast, lung, pancreas)

LEGAL FRAMEWORK

A. Jurisdiction

An individual or organization that is dissatisfied with a reconsideration of a Contractor's initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services ("Secretary") provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act § 1869(b)(1)(A). The Secretary administers the nationwide hearings and appeals system through the Office of Medicare Hearings and Appeals ("OMHA"). Administrative Law Judges ("ALJs") within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council.

A request for hearing meets the amount in controversy requirement if it comports with 42 C.F.R. § 405.1006(b)(1). A request for hearing is timely if filed within sixty days after receipt of the notice of the Qualified Independent Contractor decision. 42 C.F.R. § 405.1002(a)(1).

B. Scope of Review

"The issues before the administrative law judge include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in [the appellant's] favor. However, if evidence presented before or during the hearing causes the administrative law judge to question a fully favorable determination, he or she will notify [the appellant] and will consider it an issue at the hearing." 42 C.F.R. § 405.1032(a).

The ALJ may decide a case on the record and not conduct an oral hearing if the decision is fully favorable, or if the appellant indicates in writing that he does not wish to appear before the ALJ at a hearing. 42 C.F.R. § 405.1038.

C. Standard of Review

“The ALJ conducts a de novo review and issues a decision based on the hearing record.” 42 C.F.R. § 405.1000(d).

Principles of Law

A. Statutes and Regulations

According to § 1862(a)(1)(A) of the Social Security Act (“Act”), Medicare may not make a payment under part A or part B for anything which is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

B. Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than an NCD, can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. (*See also* 42 C.F.R. § 405.860). However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that establishes criteria for coverage of selected types of medical items and services in the form of manuals and local coverage determinations (LCDs). Administrative Law Judges are not bound by LCDs, but will give substantial deference to these policies when applicable. (42 C.F.R. § 405.1062). If an Administrative Law Judge does not follow a policy in a particular case, the Administrative Law Judge must explain why in the decision. (42 C.F.R. § 405.1062).

CMS Medicare Managed Care Manual (MMCM), 100-16, Ch. 40 sets forth specific guidance regarding Medicare cost plans.

Although not subject to the force and effect of law, CMS and its contractors issue policies, manuals and guidelines that describe criteria for coverage of selected types of medical items and services in the form of manuals and local coverage determinations (LCDs). 42 C.F.R. § 405.1062 states that an ALJ is not bound by LCDs or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. If an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed. An ALJ decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.

LCD L34823 entitled "Tumor Treatment Field Therapy (TTFT)" provides that TTFT (E0766) will be denied as not reasonable and necessary.

The undersigned notes that the LCD contains a blanket citation to authorities for support but provides no rationale, discussion or criteria upon which exceptions can be made within the context of the LCD, or upon which the LCD is based. Moreover, it does not discuss what authorities it specifically relies upon, nor what the authorities purport to state.

Policy Article A52711 provides additional guidance for TIFT, and seems to provide some inconsistent analysis with the LCD, as follows:

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed- body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary"). Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Code E0766 is in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories. Separate billing of supplies and/or accessories will be denied as unbundling.

The accompanying Policy Article establishes that TTFT is categorized under the Durable Medical Equipment benefit. The article explains that code E0766 describes "devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers." The article further states that TTFT devices are in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories. While it defers to any applicable LCD it seems to confirm categorically that in particular cases such treatments should be found to be medically reasonable and necessary. Additionally, it anticipates that any applicable LCD will provide eligibility criteria.

C. Evidence of Coverage

The Plan at issue is a Medicare Advantage Plan. The Plan's EOC states that as a Medicare health plan, the plan "must cover all services covered by Original Medicare and must follow Original Medicare's coverage rules." (Exh. 1 at 87). Covered services include "all the medical care, health care services, supplies, and equipment that are covered by our plan." (*Id.*)

ANALYSIS

After careful consideration of the evidence and arguments presented, the undersigned ALJ finds that the Novocure/Optune treatment is reasonable and necessary for purposes of coverage under Medicare Part C for the Enrollee/Beneficiary.

An MA plan must provide an enrollee with coverage for all items and services covered by Medicare Part A (except hospice services) and Part B that are available to beneficiaries in the plan's service area. See Section 1852 (a) (1) of the Social Security Act (Act); 42 C.F.R. §§422.100. An MA plan must comply with National Coverage Determinations (NCDs), general coverage guidelines included in original Medicare manuals and instructions, and written coverage decisions of local Medicare contractors with jurisdiction over claims in the geographic area in which services are covered under the MA plan. Therefore, if Medicare does not cover an item or service, unless the plan covers the item or service through supplemental benefits, the Plan is not required to cover the item or service at issue. See 42 C.F.R. § 422.102.

An LCD is program guidance developed by a Medicare contractor and is applicable only in that contractor's service area. An ALJ is not bound by program guidance such as LCDs, program memoranda, or manual instructions. However, an ALJ must give such policies substantial deference if applicable in a particular case. 42 C.F.R. § 405.1062(a). If an ALJ declines to follow a policy in a particular case, the rationale for not following that policy must be explained. 42 C.F.R. § 405.1062(b).

At the hearing Mr. Hales discussed that the beneficiary's claim for coverage was denied by Humana and the Part C QIC based on Humana's reliance on the LCD. (Hearing Record). Mr. Hales argued that TTFT treatment should be available for [redacted] because a departure from the LDC is appropriate here. (*Id.*) Mr. Hales argued that the plan was required to follow the LCD, but noted that the ALJ has the discretion to decline to follow the policy put forth in an LCD. (*Id.*) Mr. Hales stated that Humana does provide coverage for TTFT to its non-Medicare members now and noted that the FDA has approved TTFT treatment for patients with initial glioblastoma diagnoses since the LCD became active. (*Id.*) Ms. Hales then gave an overview of the present case. (*Id.*) Mr. Hales testified that the NCCN is the recommended compendia for providers of cancer treatments and noted the favorable treatment of TTFT in the NCCN and multiple published articles and journals. (*Id.*) Mr. Hales also noted the recent development of the LCD which the contractor accepted August 7, 2018. (*Id.*)

Ms. Miles testified regarding the beneficiary's symptoms and diagnosis which was glioblastoma, a very aggressive and rare form of brain cancer. (*Id.*) Ms. Miles testified that the beneficiary had radiation treatment to reduce his tumor size in December of 2016 and noted that in February of 2017 the beneficiary began TTFT. (*Id.*) Ms. Miles noted that the beneficiary is doing well clinically and stated that the most recent MRI they had for him, which was dated February 20, 2018, showed no significant changes in tumor size. (*Id.*) Ms. Miles discussed the recent acceptance by the FDA of TTFT treatment for newly diagnosed and reoccurrences of glioblastoma. (*Id.*) Ms. Miles also discussed recent studies and positive trials and noted that one study was even aborted mid-stream when it was discovered that the TTFT was so effective, it

was determined to be unfair to continue to deny the treatment to the patients in the placebo group. (*Id.*) Ms. Miles concluded by testifying regarding the benefits of TTFT and how it has impacted the glioblastoma universe through statistically significant improvement in survival rates. (*Id.*)

As mentioned above, the Provider argues that many ALJs have approved coverage of TTFT. The Provider also argues that the applicable LCD and accompanying Policy Article include only citations to outdated clinical studies and do not incorporate more successful clinical trials and studies showing the success of the TTFT treatment. The fact that many insurance companies and ALJs have approved coverage does not affect the independent judgment of the undersigned ALJ since neither insurance companies nor other ALJs decisions to coverage the TTFT treatment have precedential effect, although those determinations are noted and considered here. The undersigned ALJ does find the Provider's argument regarding updated peer review articles and clinical trials/studies to be persuasive. The Provider has pointed out that the FDA and NCCN have recently approved use of TTFT for initially diagnosed glioblastoma patients such as Mr. Stephenson. Furthermore, Humana's own internal policy dated February 22, 2018 essentially overrides the LCD with respect to coverage of this treatment being provided to Medicare Advantage Plan enrollees like Mr. Stephenson. And, Humana's non-Medicare enrollees have been covered for TTFT treatment for a while.

Pursuant to 42 C.F.R. § 405 .1062, Medicare regulations permit an ALJ to decline to follow a local coverage policy in individual cases if he/she sets forth specific reasons. After carefully weighing all of the factors in this case, the undersigned ALJ declines follow the applicable LCD L34823 in this particular case.

The undersigned ALJ agrees with the Provider's contention that the citations and authorities relied upon in LCD L34823 are outdated and do not necessarily reflect the current consensus of the medical community. Indeed, Humana's own internal Medicare policy, evidently overlooked by the employees who were reviewing this particular appeal, has changed to accept TTFT as an appropriate treatment which should be covered when certain patient criteria are met – and those criteria are met by n. The evidence in the record indicates that the TTFT treatment has increased s life span and is more likely than not going to continue to increase his life span survival by several months or more.

As discussed above, the applicable LCD L34823 does not consider or address recent breakthrough results or generally accepted consensus from the medical community. For these reasons, the undersigned ALJ declines to follow the applicable LCD in this case.

The undersigned ALJ finds that the TTFT device known as Optune is medically reasonable and necessary for the Enrollee/Beneficiary. Humana must provide coverage for the TTFT at issue. The medical record contains sufficient documentation of the Enrollee/Beneficiary's medical diagnosis of malignant neoplasm of the brain to substantiate the medical reasonableness and necessity for the Optune treatment at issue, satisfying Medicare rules and regulations.

CONCLUSION OF LAW

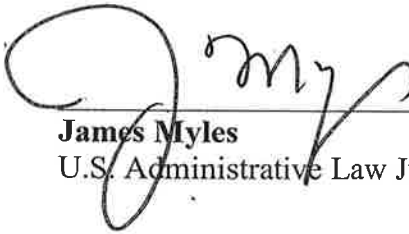
In accordance with the Plan's EOC and the Plan's February 22, 2018 internal policy update, and based on the ALJs reasoning with regard to departure from the applicable LCD, the Plan is required to pre-approve Tumor Treatment Field Therapy for Appellant/Enrollee.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated: SEP 13 2018


James Myles
U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Cleveland Field Office
Cleveland, Ohio

Appeal of:		ALJ Appeal No.:	1-669 628 2532
Representative:	Novocure, Inc.		
Beneficiary:			Medicare Part C
HICN:	*****5219A	Before:	James S. O'Leary U.S. Administrative Law Judge
Medicare Part C Advantage Plan Operator:	Presbyterian Health Plan, Inc.		

DECISION

After carefully considering the documentary and testimonial evidence in the Record, this **FAVORABLE** Decision is issued to Appellant and Beneficiary, determining that her Medicare Part C Advantage Plan operated by Presbyterian Health Plan, Inc. ("Plan") is required to provide Medicare coverage for the services of Novocure, Inc. in providing treatment with an Optune device, formerly known as a NovoTTF ("TT Fields") device ("Optune device") (E0766), to treat Appellant's glioblastoma.

Procedural History

This case is before the Office of Medicare Hearings and Appeals ("OHMA") on appeal following an unfavorable decision issued by MAXIMUS Federal Services, Medicare Part C contractor ("QIC"). (Ex. 1/1-5) The Administrative Law Judge ("ALJ") has carefully considered all the evidence in the Record.

In its June 23, 2017 Notice of Denial of Medical Coverage, the Plan denied the requested device, stating it is not covered by Medicare and is considered not medically necessary. (Ex. 1/35-38) In its July 24, 2017 Redetermination Decision, the Plan decided that its first decision to deny coverage for the request for a six month rental for an Optune Device and Transducer Arrays was right, stating that documentation submitted by Dr. _____ does not support a medical necessity for the requested device; and the requested device is not covered by Medicare. (Ex. 1/13-14)

In its August 22, 2017 Reconsideration Decision, the QIC determined that the Plan did not have to pre-approve an Optune device (E0766) rental, stating that the Medicare rules at 42 C.F.R. §422.101 say that Medicare Part C health plans must pay for a medical service or item if

regular Medicare would pay for it in this case; and Local Coverage Determination Tumor Treatment Field Therapy (TTFT) V14 - I.34823 (Rev. Eff. 01/01/2017) states Medicare will deny tumor treatment field therapy (E0766) as not reasonable and necessary. (Ex. 1/1-5) On August 25, 2017, OMHA received Appellant's request for an ALJ hearing. (Ex. 3/1) The amount in controversy exceeds the requisite amount to establish jurisdiction and this matter is properly before the undersigned ALJ. 42 C.F.R. § 405.1006.

On October 20, 2017, the undersigned ALJ held a hearing in this case. Participating were Appellant's wife ; and Appellant's treating oncologist, MD. Representatives of Novocure, Inc. who participated were Stephanie Hales, Esq., counsel; Dan McCoy; Justin Kelly, RN, Senior Director of Medical Policy; and Jorge Morales, Case Manager. On behalf of the Plan, the following participated: Erica Chavez, Esq., counsel; Dr. Norman White, Senior Medical Director; Melissa Banik, Medicare Program Director; and Meagan Curley-Martinez, Regulatory Coordinator. The undersigned ALJ said he was admitting into the Record as Exhibit 5 was "new evidence" submitted by the Plan. This evidence is actually clearer copies of previously submitted documentation. The exhibits were admitted into the Record without objection.

Issue

The issue is whether Appellant's Medicare Part C Advantage Plan operated by Presbyterian Health Plan, Inc. ("Plan") is required to cover the services of Novocure, Inc. in providing treatment with an Optune device, formerly known as a TT Fields device ("Optune device"), to treat Appellant's glioblastoma.

Findings of Fact

Hearing

Mr. Kelly described the Optune device produced by Novocure, Inc. as a portable medical device approved by the FDA to be used for the treatment of recurrent and newly diagnosed glioblastoma in combination with chemotherapy. The device generates tumor treating electrical fields to four transducer arrays that are placed on the patient's scalp. Medicare has classified the device as durable medical equipment ("DME") and given it HCPCS code E0766. Mr. Kelly said the FDA originally approved the Optune device in 2011 for recurrent glioblastoma and in 2015 for newly diagnosed glioblastoma. The FDA approvals were based on clinical studies that showed that the Optune device increased progression free survival and overall survival in glioblastoma patients. Mr. Kelly said a lot of commercial health insurance policies and some state Medicaid programs cover the Optune device.

Dr. described glioblastoma as the most common form of primary brain cancer. Glioblastoma tumors are highly aggressive. Dr. said, "There are limited treatment options" for this type of tumor. He said the Optune device is the first therapy approved by the FDA to treat glioblastoma since 2005. Dr. testified that he is one of Appellant's treating oncologists at the University of New Mexico Hospital. He said that Appellant had presented with a

glioblastoma on his left frontal lobe in early 2017, had undergone surgery, and then had radiation with chemotherapy with Temozolomide (Temodar). After that, [redacted] had severe myelosuppression and could not use Temodar. Dr. [redacted] said the only other option was for Mr. [redacted] to use the Optune device. Dr. [redacted] said that [redacted] has been using the Optune device for six months. As to its efficacy, he said they had not done any MRI scans, but they plan to do them next week. Dr. [redacted] said that based on current observation, Mr. [redacted] is doing amazingly well, and he has not seen any decline in Mr. [redacted] quality of life. He said [redacted] has had minimal side effects, other than scalp irritation.

Appellant's wife, [redacted] testified that she has been married to Appellant [redacted] for 65 years. She said her husband is a very active 80 year old. After serving in the Air Force, [redacted] worked as a mechanical engineer. Since his retirement, he has written six books. He has also done volunteer work in search and rescue for seven years. She said that her husband underwent surgery for his glioblastoma on February 1, 2017. His tumor was in the area of the brain controlling language, and after surgery, he had aphasia and ataxia which was frustrating for him, and he had to re-learn self-expression. She said the Optune device is her husband's treatment option, because he is unable to have any more chemotherapy. She said her husband's quality of life is very good, and she and her husband would like to continue the use of the Optune device as long as possible.

Ms. Hales, counsel for Novocure, Inc., said that the Plan was bound to follow the Local Coverage Determination but pointed out that the undersigned ALJ must give it substantial deference. She said all four of the Medicare Administrative Contractors ("MAC's") have issued the identical LCD on the Optune device. She said the FDA has approved the Optune device to treat recurrent and newly diagnosed glioblastoma. She said the National Comprehensive Cancer Network ("NCCN") has recommended the Optune device to treat recurrent and newly diagnosed glioblastoma.

On behalf of the Plan, Dr. White said the Plan's denial of coverage of the Optune device to treat [redacted] glioblastoma is based on the LCD, stating that it is not reasonable and necessary and is not covered by Medicare. Dr. White said the Plan reviewed other sources in making its decisions, including Hayes, Inc. which provides analyses of healthcare treatments based on a review of peer-reviewed medical literature. In this case, Hayes, Inc. said the data is not there to support the use of the Optune device in glioblastoma treatment.

Documentation

Appellant [redacted] an 80-year-old man, initially presented with confusion, right-sided weakness and grand mal seizure in February 2017, and a diagnostic work-up showed he had a left frontal lobe brain tumor measuring 3.1 x 2.7 x 2.7 centimeters. (Ex. 2/3-7) On February 1, 2017, he underwent surgical resection, and the biopsy showed glioblastoma multiforme, MGMT promoter methylation negative, and IDH1 and IDH2 negative. (*Id.*) "Postoperative MRI on February 2, 2017 indicated no convincing evidence of residual enhancing neoplasm." (*Id.*) He received concurrent chemoradiation therapy with Temodar from March 21-April 10, 2017. (Ex. 2/1-2)

Appellant had a May 9, 2017 restaging MRI, indicating there was enhancement along the margin of the resection cavity, as follows:

On MRI of the brain done on May 9, 2017, there was evidence of curvilinear nodular enhancement along the margin of the resection cavity concerning for residual recurrent disease. Also, a focal nodule of restricted diffusion and enhancement along the posterolateral margin of the cavity concerning for hypercellular tumor.

(Ex. 2/8-13) When he saw his physicians in mid-May 2017, his clinical status was believed to be “stable if not improving.” (*Id.*) The plan was to begin adjuvant Temodar “with a relatively short followup on an MRI to reevaluate.” (*Id.*) However, at the time of his mid-May 2017 visit, his ANC was 1.3 and his platelets were 38,000, and he was not started on Temodar® (Temozolomide). (*Id.*) He was seen on May 31, 2017 for follow-up, and “the patient’s blood counts, again, have not recovered to adequate levels to make starting Temodar safe.” (*Id.*)

M.D., Appellant’s hematologist oncologist, recommended that the Appellant be followed conservatively and that his CBC’s be checked on a weekly basis. (*Id.*) Appellant and his wife had some questions and concerns about the Optune treatment device that Dr. had discussed with them briefly at the time of their last visit. (*Id.*) At the time of the May 31, 2017 visit, further discussion of the Optune device was deferred. (*Id.*)

Glioblastoma Multiforme

“Malignant gliomas are heterogenous, highly invasive primary brain tumors. Glioblastoma multiforme (GBM), classified by World Health Organization (WHO) as a grade IV glioma, is particularly aggressive. Most patients diagnosed with this tumor die within one year from the diagnosis and only 5% survive more than 5 years despite aggressive therapies. Over the last decade, a variety of different treatments were explored with very limited success.” Maciej M. Mrugala, “Advances and Challenges in the Treatment of Glioblastoma: A Clinician’s Perspective,” April 25, 2013, *Discovery Medicine* available at <http://www.discoverymedicine.com/Maciej-M-Mrugala/2013/04/25>.

The standard treatment for glioblastoma multiforme is described, as follows:

Upon initial diagnosis of glioblastoma multiforme (GBM), standard treatment consists of maximal surgical resection, radiotherapy, and concomitant and adjuvant chemotherapy with temozolomide.^{[1], [25]} For patients older than 70 years, less aggressive therapy is sometimes employed, using radiation or temozolomide alone.^{[26], [27], [28]} A study by Scott et al found that elderly patients with glioblastoma who underwent radiotherapy had improved cancer-specific survival and overall survival compared with those who did not undergo radiotherapy treatment. [29]

....

Median time to recurrence after standard therapy is 6.9 months. [45] For recurrent glioblastoma multiforme, surgery is appropriate in selected patients, and various radiotherapeutic, chemotherapeutic, biologic, or experimental therapies are also employed. [46, 36]

....

The responsiveness of glioblastoma multiformes to radiotherapy varies. In many instances, radiotherapy can induce a phase of remission, often marked with stability or regression of neurologic deficits as well as diminution in the size of the contrast-enhancing mass. Unfortunately, any period of response is short-lived because the tumor typically recurs within 1 year, resulting in further clinical deterioration and the appearance of an expansile region of contrast enhancement. [55, 56]

....

Temozolomide is an orally active alkylating agent that is used for persons newly diagnosed with glioblastoma multiforme. It was approved by the United States Food and Drug Administration (FDA) in March 2005. Studies have shown that the drug was well tolerated and provided a survival benefit. Adjuvant and concomitant temozolomide with radiation was associated with significant improvements in median progression-free survival over radiation alone (6.9 vs 5 mo), overall survival (14.6 vs 12.1 mo), and the likelihood of being alive in 2 years (26% vs 10%).

....

Chemotherapy for recurrent glioblastoma multiforme provides modest, if any, benefit, and several classes of agents are used. Carmustine wafers increased 6-month survival from 36% to 56% over placebo in one randomized study of 222 patients, though there was a significant association between the treatment group and serious intracranial infections. [80, 81]

Jeffrey N. Bruce, MD; "Glioblastoma Multiforme Treatment & Management;" Updated: June 14, 2017; Medscape available at <https://emedicine.medscape.com/article/283252>.

Chemoradiation has been the standard treatment for glioblastoma multiforme since 2005, as follows:

Following optimal surgical resection, the patient commonly waits as many as four weeks for the craniotomy wound to heal before starting therapy. Postoperative radiation therapy (RT) alone was standard treatment until 2005, when the results of a pivotal phase III trial changed the standard of care for GBM. This trial confirmed that external beam RT with concomitant TMZ chemotherapy (known as the Stupp regimen) was more effective than RT alone (Stupp et al., 2005). Patients who received TMZ plus RT had a median survival of 14.6 months versus 12.1 months with RT alone. The survival advantage remained because the TMZ plus RT cohort had a higher proportion of long-term survivors than the RT alone

group with 27% versus 11% at two years and 10% versus 2% at five years, respectively (Stupp et al., 2009). The analysis of this trial also led to the identification of another strong predictor of patient-related outcomes: the methylation of the MGMT gene, located on chromosome 10q26. MGMT codes for an enzyme involved with DNA repair. Patients who have methylated (not activated) MGMT exhibit compromised DNA repair. When the MGMT enzyme is activated, it can interfere with the effects of treatment. RT and alkylating chemotherapy exert their therapeutic effects by causing DNA damage and cytotoxicity and triggering apoptosis. Therefore, the expression of methylated MGMT is beneficial for patients undergoing TMZ chemotherapy and RT. In the trial by Stupp et al. (2009), methylation of MGMT was a strong predictor of better outcomes from TMZ treatment.

Mary Elizabeth Davis, RN, MSN, CHPN, AOCNS, "Glioblastoma: Overview of Disease and Treatment;" Oct.1, 2016; *Clinical Journal of Oncology Nursing* available at <https://www.ncbi.nlm.nih.gov>.

The absence of IDH1 and IDH2 in Appellant's glioblastoma impair prognosis, as follows:

Mutations in isocitrate dehydrogenase (IDH) 1 and 2, originally discovered in 2009, occur in the vast majority of low grade gliomas and secondary high grade gliomas. These mutations, which occur early in gliomagenesis, change the function of the enzymes, causing them to produce 2-hydroxyglutarate, a possible oncometabolite, and to not produce NADPH. IDH mutations are oncogenic, although whether the mechanism is through alterations in hydroxylases, redox potential, cellular metabolism, or gene expression is not clear. The mutations also drive increased methylation in gliomas. Gliomas with mutated IDH1 and IDH2 have improved prognosis compared to gliomas with wild-type IDH. Mutated IDH can now be detected by immunohistochemistry and magnetic resonance spectroscopy. No drugs currently target mutated IDH, although this remains an area of active research.

Adam Cohen, M.D., Sheri Holmen, PhD, and Howard Colman, MD, PhD; "IDH1 and IDH2 Mutations in Gliomas; 2013 May; 13(5):345; *Current Neurological and Neuroscience Reports* available at <https://www.ncbi.nlm.nih.gov>.

Optune Device

The Tumor Treating Fields Therapy provided by an Optune device, is described as follows:

Tumor treating fields (TTFs) therapy uses alternating electric fields to inhibit cell proliferation and lead to programmed cell death. TTF therapy targets dividing cells to stop tumor growth while sparing normal tissue. The Optune™

TTF system is intended to treat patients with glioblastoma by using transducer arrays placed on the patient's scalp according to the tumor's location. Patients use the device on an outpatient basis for at least 18 hours per day for 4 weeks to several months. Intended benefits include stabilizing the disease, having fewer treatment-related adverse events, and improving quality of life. A potential disadvantage is skin irritation.

Novocure leases Optune Treatment Kits to patients. The total monthly therapy cost is about \$21,000, or about \$86,000 when used an average of 4.1 months (median treatment duration) for the typical patient. . . .

"Tumor Treating Fields Therapy (Optune) for Recurrent Glioblastoma." *ECRI Institute, Health Technology Assessment Information Service™*, November 2015, Emerging Technology Evidence Report.

Since 2015, the NCCN had given the Optune device a 2B recommendation (indicating that there is an NCCN consensus that the intervention is appropriate) for recurrent GBM patients in combination with Temodar (Temozolomide). Andrew J. Roth, "NCCN Strengthens Recommendation for Optune in Glioblastoma Multiforme;" *CureToday* available at <https://www.curetoday.com>. In July 2016, the National Comprehensive Cancer Network ("NCCN") gave the Optune device a 2A recommendation (indicating that there is a uniform NCCN consensus that the intervention is appropriate) to treat newly diagnosed glioblastoma multiforme ("GBM") patients in combination with Temodar (Temozolomide). (*Id.*)

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act § 1869(b)(1)(A). In implementing this statutory directive, the Secretary has delegated his authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *Id.* A hearing before an ALJ is only available if the amount in controversy meets the statutory jurisdictional limit. 42 Code of Federal Regulations (CFR) §405.1006 (b); 72 Federal Register 73348 (December 27, 2007). The request for hearing is timely if filed within sixty days after receipt of a Qualified Independent Contractor decision. *See* 42 CFR §405.1002.

B. Scope of Review

The issues before the administrative law judge include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in [the appellant's] favor. However, if evidence presented before or during the hearing causes the administrative law judge to question a fully favorable determination, he or she will notify the appellant and will consider it an issue at the hearing. 42 CFR §405.1032.

C. Standard of Review

"The [Office of Medicare Hearings and Appeals] . . . is staff[ed] with Administrative Law Judges who conduct 'de novo' hearings . . ." 70 Fed. Reg. 36386 (June 23, 2005); *see also In re Atlantic Anesthesia Associates, P.C.*, MAC (June 2004) ("An [ALJ] qualified and appointed pursuant to the Administrative Procedure Act acts as an independent finder of fact in conducting a hearing pursuant to section 1869 of the Act. This requires *de novo* consideration of the facts and law.").

II. Principles of Law

A. Statutes

The Medicare Act (the Act), establishes a federally subsidized health insurance program to be administered by the Department of Health and Human Services (HHS). Part A of the Act provides insurance for the cost of hospital and related post-hospital services. (42 U.S.C. § 1395c *et seq.*) Sections 1812 and 1813 of the Act establish benefits under Medicare Part A. Section 1814 establishes conditions and limitations on payment for services furnished by providers. The Medicare program, Title XVIII of the Act, is administered through the Centers for Medicare and Medicaid Services, a component of the HHS). Under the authority of Section 1842(a)(1)(A) of the Act, the Secretary of HHS is authorized to enter into contracts with private entities for the day-to-day operations of the program.

The Social Security Act at Part B established Supplementary Medical Insurance Benefits, Act §1831. It is a voluntary insurance program to provide medical insurance benefits in accordance with the provisions of Part B for aged and disabled individuals who elect to enroll and pay premium payments. *Id.* Section 1862(a)(1) of the Act provides that no payment may be made under Medicare Part A or Part B for any expenses incurred for items or services which "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." (42 U.S.C. § 1395y (a)(1)(A), 42 CFR 411.15(k)(1)). Section 1833(e) of the Act and CMS Regulations provide that claims for payment must be supported by sufficient information and documentation (42 CFR 424.5(a)(6)). Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than an National Coverage Determination (NCD), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. *See also* 42 C.F.R. §405.860. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the

form of manuals and local medical review policies ("LMRPs") or local coverage determinations ("LCDs"). Section 1879 of the Act provides for a limitation on liability in certain instances when neither the provider nor beneficiary could have known, nor could be reasonably expected to have known, that the services would not be covered by Medicare. A provider or supplier is also considered to have notice that services are not covered if they inform the beneficiary that the services are not covered by Medicare (42 CFR 411.406(d)). A provider or supplier is also considered to have notice that services are not covered if it is clear that they could have been expected to know that from their receipt of notices from CMS or its agents, publication in the Federal Register, or based on their "knowledge of what are considered acceptable standards of practice by the local medical community" (42 CFR 411.406(e)).

Pursuant to the Act § 1832(a), the Part B Supplementary Insurance Program entitles its enrollees to have payment made to them or on their behalf for "medical and other health services" listed in § 1832(a), with certain exceptions. Pursuant to the Act, § 1861(s), the term "medical and other health services" includes the following items:

(5) surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations;

(6) durable medical equipment;

(8) prosthetic devices (other than dental which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens;

(9) leg, arm, back and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition;

Section 1861(n) defines "durable medical equipment" as follows:

The term "durable medical equipment" includes iron lungs, oxygen tents, hospital beds, and wheelchairs used in the patient's home, whether furnished on a rental basis or purchased, and includes blood-testing strips and blood glucose monitors for individuals with diabetes without regard to whether the individual has Type I or Type II diabetes or to the individual's use of insulin (as determined under standards established by the Secretary in consultation with the appropriate organizations);

The payment rules for particular items and services identified in § 1861 are found in the Act, § 1834.

B. Regulations

The Supplementary Medical Insurance Program under Medicare Part B, helps pay for "medical and other health services." 42 C.F.R. § 410.3(a)(1). "Medical and other health services" include services and supplies, including medical services, equipment and supplies that are not covered under the Medicare Part A hospital insurance program (42 C.F.R. § 410.3(a)(3)); and include services and supplies furnished incident to a physician's professional services, of kinds commonly furnished in physician offices and are commonly, furnished without charge, and include "medical supplies, appliances, and devices (42 C.F.R. § 410.10(b) and (g)). Specifically, Medicare's coverage for "medical supplies, appliances and devices" includes surgical dressings. 42 C.F.R. § 410.36(b). In order to implement the statutory scheme established by Congress under the Act, the Secretary of the Department of HHS promulgated regulations, known as the Code of Federal Regulations (C.F.R.), at 42 C.F.R. §§ 400 through 1008.59. Act § 1871. The Secretary of HHS has the authority to prescribe regulations to carry out the administration of the Medicare insurance programs. Act § 1871(a)(1). Section 1871(a)(2) of the Act provides that no rule, requirement or statement of policy, other than a National Coverage Determination (NCD), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program unless it is promulgated as a regulation by the Secretary. However, although not subject to the force and effect of the law, CMS and its contractors, have issued policy and guidelines that describe criteria for coverage for selected types of medical services and supplies. Medicare shall not retroactively apply a substantive change in regulations, manual instructions, interpretive rules, statements of policy or guidelines of general applicability under the Act. Act § 1871(e)(1)(A).

C. Policy

Section 1871(a)(2) of the Act provides that no rule, requirement or statement of policy, other than a national coverage determination, can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program unless it is promulgated as a regulation by CMS. However, although not subject to the force and effect of the law, CMS and its contractors, have issued policy and guidelines that describe criteria for coverage for selected types of medical services and supplies. Administrative Law Judges may also give consideration to the manuals and rulings issued by CMS in determining benefit coverage and eligibility. An ALJ is not bound by manuals, program memoranda and other issuances created by CMS; however, an ALJ must accord substantial deference to them as valid interpretive rules that clarify the application of statutory and regulatory requirements. In *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87 (1995), the United States Supreme Court concluded that an agency manual section was a valid interpretive rule and also found that it was reasonable for the agency to follow it. *Id.* at 102.

In order to be covered by Medicare, an item or service must be determined to be "reasonable and necessary" for the diagnosis or treatment of an illness or injury, and "reasonable and necessary" is defined in the *Medicare Program Integrity Manual*, as follows:

§13.5.1 – Reasonable and Necessary Provisions in LCDs (Rev. 71, 04-09-04)(Eff. 05/10/04)(Imp. 05/10/04)

A service may be covered by a contractor if:

- It is reasonable and necessary under 1862(a)(1)(A) of The Act.

Only reasonable and necessary provisions are considered part of the LCD.

Reasonable and Necessary

In order to be covered under Medicare, a service shall be reasonable and necessary. When appropriate, contractors shall describe the circumstances under which the proposed LCD for the service is considered reasonable and necessary under 1862(a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
- Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
 - o Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
 - o Furnished in a setting appropriate to the patient's medical needs and condition;
 - o Ordered and furnished by qualified personnel;
 - o One that meets, but does not exceed, the patient's medical need; and
 - o At least as beneficial as an existing and available medically appropriate alternative.

There are several exceptions to the requirement that a service be reasonable and necessary for diagnosis or treatment of illness or injury.

CMS, *Medicare Program Integrity Manual (MPIM) (Internet-Only Manual Publ'n 100-08)*, ch. 13, §13.5.1.

CGS Administrators, LLC, DME MAC Jurisdiction C, Local Coverage Determination L34823: *Tumor Treatment Field Therapy (TTFT)* (V14) (Rev. Eff. 01/01/2017), sets forth the following Medicare coverage rule:

Indications and Limitations of Coverage and/or Medical Necessity

....

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

(LCD L34823)

Analysis

This decision is favorable.

Appellant, an 80-year-old man, was diagnosed with a left frontal brain tumor in January 2017. On February 1, 2017, Appellant underwent surgery to remove the tumor. The biopsy revealed glioblastoma multiforme ("GBM") with no MGMT promotor methylation and no IDH1 or IDH2 mutations. From March 21-April 10, 2017, he underwent concurrent chemoradiation therapy with Temodar (Temozolomide). On May 9, 2017, Appellant's brain MRI showed evidence of residual recurrent disease. His treating physicians had planned to administer adjuvant Temodar, but at his visits in mid-May 2017 and May 31, 2017, his blood counts were too low to permit the chemotherapy to be given. During the ALJ hearing, it was learned that Mr. [redacted] had been receiving Tumor Treatment Field Therapy ("TTFT") with Novocure, Inc.'s Optune device for the previous six months.

Representatives of Novocure, Inc. testified during the hearing about the Optune device. It has been FDA approved to treat recurrent GBM since 2011 and to treat newly diagnosed GBM since 2015 in combination with chemotherapy with Temodar. The National Comprehensive Cancer Network ("NCCN") has given the Optune device a 2A recommendation for treating newly diagnosed GBM in combination with Temodar and a 2B recommendation for treating recurrent GBM in combination with Temodar.

Medicare's Local Coverage Determinations, including LCD L34823, regarding Tumor Treatment Field Therapy state unequivocally that there is no Medicare coverage for such treatment, as follows:

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

The LCD does not contain any further information or reasons for this denial.

In this case, [redacted] has been unable to have additional treatment with Temodar due to his low blood counts, severely limiting his treatment options. In addition, his tumor has no MGMT promotor methylation which would have given him a significant survival benefit when treated with Temodar. Also, his tumor lacks IDH1 and IDH2 mutations which would have given him an improved prognosis. Although the undersigned ALJ must give substantial deference to

LCD L34823, the LCD is not applicable to the present circumstances where the treatment with the Optune device is Appellant's only treatment option. Under these circumstances, the Plan is required to cover his requested treatment with the Optune device.

Conclusions of Law

Pursuant to Title XVIII of the Social Security Act, and implementing regulations and Medicare manuals, the undersigned ALJ has determined that Appellant's Medicare Part C Advantage Plan operated by Presbyterian Healthcare is required to provide Medicare coverage for the services of Novocure, Inc. in providing treatment with an Optune device, formerly known as a NovoTTF ("TT Fields") device (E0766), to treat Appellant's glioblastoma.


ORDER

The Medicare contractor is directed to process the claim in accordance with this decision.

SO ORDERED.

Dated: _____

NOV 01 2017



James S. O'Leary

U.S. Administrative Law Judge

Enclosures: Form OMHA-156, *List of Exhibits*



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Cleveland, Ohio

Appeal of:	OMHA Appeal No.: 1-7738136436
Beneficiary:	Medicare: Part B
Medicare No.:	Before: Joseph F. Petrylak Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, a **FAVORABLE** decision is entered for the Appellant.

Procedural History

(hereinafter, the Appellant), submitted a claim to the Medicare to be reimbursed under Medicare Part B for durable medical equipment (DME) specifically, Tumor Treatment Field Therapy (TTFT) with Novocure Novo-TTF 100A Plus Transducers (E0766) provided to the Appellant on August 3, 2017, September 3, 2017, and October 3, 2017.

The claim was initially denied by the Medicare contractor. On December 1, 2017, the Medicare Administrative Contractor upheld the denial on redetermination. Exh. 1, pp. 13-16. On June 15, 2018, the QIC issued an unfavorable reconsideration and determined that the documentation did not meet the requirements of the LCD L34823, that the medical record did not support the need for the device, and that there was insufficient medical literature to clearly demonstrate the effectiveness of the device. Exh. 1, pp. 1-5. The Supplier, Novocure, was held liable for the cost of the uncovered device. *Id.*

The Office of Medicare Hearings and Appeals received the Appellant's timely filed appeal on August 2, 2018. Exh. 3, pp. 1-7, Master CD. Claims have been consolidated as requested by the Appellant. *Id.* The amount in controversy satisfies the jurisdictional requirement for an Administrative Law Judge (ALJ) hearing pursuant to Title XVIII of the Social Security Act (Act) § 1869(b)(1)(E) and 42 C.F.R. § 405.1006.

The Appellant submitted documentation to the Administrative Law Judge after the decision from the QIC. The Administrative Law Judge has found that good cause existed for the late submission of this evidence and the evidence has been entered into the record at Exhibit 5.

An administrative hearing was held by telephone on October 17, 2018. The Appellant was represented by counsel, Debra M. Parrish, Esq. At the hearing, Julie Miles, RN, Novocure Clinical Specialist, testified for the Appellant. All exhibits were admitted into evidence without objection and were considered in reaching this decision.

Issue

The issue on appeal is whether payment may be made for Tumor Treatment Field Therapy (TTFT) with Optune, also known as Novo-TTF 100A Plus Transducers (E0766) provided to the Appellant on August 3, 2017, September 3, 2017, and October 3, 2017.

Findings of Fact

In November 2015, the Appellant, a 72-year-old male, presented to the ER following loss of consciousness and a seizure-like episode. Exh. 2, pp. 109-111. He was subsequently found to have ring-enhancing lesions of the brain. *Id.* CT scans of the brain showed no evidence of hemorrhage. *Id.* On December 2, 2015, the Appellant underwent a biopsy of the left frontoparietal lobe with stereotactic techniques. *Id.* The Appellant, was diagnosed with left frontoparietal glioblastoma (Grade IV glioma). *Id.* A follow-up consult with oncology deemed that his tumor was non-operable. *Id.* He was initiated on an accelerated course of external beam radiation therapy, with a course of temozolomide concomitantly with radiation therapy. *Id.* The Appellant also received multiple cycles of Temodar. *Id.*

On May 2, 2017 Dr. _____ from the Crouse Neuroscience Institute prescribed the use of Optune, formerly called Novo TTF-100A system for 6 months to treat the Appellant's glioblastoma, ICD-9 code C71.9. Exh. 2, pp. 16-17. On August 21, 2017, the doctor authored a letter that sought authorization of coverage and payment from the Appellant's medical provider. Exh. 2, pp. 1-3. In the letter of medical necessity, the doctor indicated that the beneficiary was a good candidate for treatment. *Id.* The letter further indicated that the FDA had approved use of the device for treatment in adult patients with histologically-confirmed glioblastoma multiforme, following histologically or radiologically confirmed recurrence in the supra-tentorial region of the brain after receiving chemotherapy. *Id.* In addition he referred to the National Comprehensive Cancer Network (NCCN) Guidelines which had been updated in 2015 to include TTFT treatment for recurrent glioblastoma. The NCCN category 2A recommendation included alternating Optune with adjuvant temozolomide following standard radiation therapy. *Id.*

The doctor indicated that there were few, if any, available options to the Appellant. He argued that Optune is currently the only chronic treatment option for recurrent glioblastoma that has established its survival benefits and safety profile in a randomized controlled trial against a control arm receiving the active therapy, Avastatin. *Id.* The doctor indicated Avastatin, had never been studied in a randomized trial for recurrent glioblastoma and had not demonstrated a survival time benefit in that population. *Id.* It was his opinion that the Optune system was the only viable treatment option for the Appellant *Id.*

The Appellant received education and training on the use of his system on August 3, 2016. Exh. 2, pp. 18-21.

Legal Framework

I. Administrative Law Judge Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) § 1869(b)(1)(A).

In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *Id.*

A hearing before an ALJ is only available if the remaining amount in controversy is \$130 or more. *See* 42 C.F.R. § 405.720, 42 C.F.R. § 405.1002, and 42 C.F.R. § 405.1006. The request for hearing is timely if filed within sixty days after receipt of a QIC decision. *See* 42 C.F.R. § 405.722 and 42 C.F.R. § 405.1002.

B. Scope of Review

“The issues before the ALJ include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in a party’s favor . . . However, if evidence presented before the hearing causes the ALJ to question a favorable portion of the determination, he or she notifies the parties before the hearing and will consider it an issue at the hearing.” 42 C.F.R. § 405.1032.

“If the evidence in the hearing record supports a finding in favor of appellant(s) on every issue, the ALJ may issue a hearing decision without giving the parties prior notice and without holding a hearing.” 42 C.F.R. § 405.1038.

A Medicare Part A Administrative Law Judge Hearing is governed by the procedures set forth at 42 C.F.R. §§ 405.1000 through 405.1054.

C. Standard of Review

The Office of Medicare Hearings and Appeals Administrative Law Judges “conduct impartial ‘de novo’ hearings.” 70 Fed. Reg. 36386 (June 23, 2005).

II. Principles of Law

A. Statutes

Title XVIII § 1832 of the Social Security Act describes the scope of the benefits provided to beneficiaries under Medicare Part B, which includes medical and other health services. Title XVIII

§ 1861 provides that “medical and other health services” includes durable medical equipment and supplies.

Title XVIII § 1833(e) of the Social Security Act provides that no payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

Title XVIII § 1862(a)(1)(A) of the Social Security Act provides that, “Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services . . . which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”

Section 1879 of the Act provides that when Medicare coverage and payment is excluded pursuant to Section 1862(a)(1) or (a)(9), payment may nevertheless be made for items or services, if neither the beneficiary nor the provider or supplier knew, and could not reasonably be expected to have known, that the items or services would not be covered or payable by Medicare.

B. Policy and Guidance

CMS, *Medicare Program Integrity Manual (MPIM) (Internet-Only Manual Publ’n 100-08)* Ch. 5, § 5.7, provides in pertinent part:

For any DMEPOS item to be covered by Medicare, the patient’s medical record must contain sufficient documentation of the patient’s medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the patient’s diagnosis and other pertinent information including, but not limited to, duration of the patient’s condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc.

Local Coverage Determinations (LCDs) are developed by Medicare contractors to help determine whether certain items or services are covered. These LCDs are binding on the Medicare contractors in determining what items are covered but are not binding on ALJs. However, they are required to be given substantial deference by an ALJ and any failure to follow an LCD must be explained.

Local Coverage Determination, L34823 addresses tumor treatment field therapy (TTFT).

The LCD states:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory

requirements. For the items addressed in this local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

Analysis

On appeal, the QIC denied payment for Novocure TTF 100-A device and transducer array supplies at issue on the basis that the coverage requirements were not met. Exh. 1, pp. 4-7. Specifically the QIC stated that there was insufficient documentation to quantify the effect of the device for this beneficiary, and that the medical records did not support why the beneficiary needed this treatment. *Id.* At the redetermination, the payment was denied because the supplier used a miscellaneous billing code and did not furnish documentation with the manufacturer name, and suggested retail price. Exh. 1, p 15. The appellant contends the documentation submitted meets coverage criteria for the Novo TTF 100-A system and transducer arrays supplies (E1399, A9999). Exh. 3, pp. 25-26. After careful review of the record, the ALJ disagrees with the QIC and finds that there is sufficient documentation to meet the requirements for Medicare payment of the Novo TTF 100-A system and transducer arrays supplies (E1399, A9999).

At hearing, Deborah Parrish, Esq. (the Appellant's attorney) and Julie Miles, RN made the following presentation: Ms. Parrish acknowledged that the QIC denied the payment for the Appellant's treatment based on three issues: the medical documentation did not quantify the effectiveness of the device; there was not sufficient medical literature to support the effectiveness of the device; and the LCD L34823 states that TTFT will be denied as not medically necessary. She argued that the effectiveness of the TTFT is self-evident and should be quantifiable by simply counting the number of months beyond the standard 10 months of life expectancy for patients with glioblastoma. The Appellant was first diagnosed in December of 2015, but he continues to survive almost three years later. Second, she disputed that there is not sufficient scientific literature and reiterated that the device has received FDA approval and is the only example of the Data and Safety Monitoring Board to recommend early termination of clinical trials so that patients in the control arm could switch over to treatment. This decision was reached because of the unquestionable effectiveness of the device. In the scientific literature, Optune treatment results have been classified as level I evidence which indicates that the scientific community has 100% consensus on the effectiveness of the treatment. She also noted that the National Cancer Guidelines have been updated to include Optune as the recommended treatment for glioblastoma, it has been prescribed in all 50 states, and is the standard of care for glioblastoma. Third, she argues that the LCD is not controlling. It has not been updated since 2013, is very out of date, and should not be applied to cases of newly diagnosed glioblastoma. With reference to the policy article 52711, Ms. Parrish stated that her interpretation requires payment standards to revert back to general Medicare coverage requirements and that Optune treatment has met all of those requirements. Lastly, Ms. Parrish noted that the Medicare coding assignment of Tumor treatment field therapy (E0766) is in itself an acknowledgement that the treatment has been accepted in the medical community and was being widely used. The treatment would never have been assigned a code if it was still considered experimental. (Hearing CD.)

Ms. Julie Miles testified with regards to the medical records of the Appellant. She noted that there are only approximately 10,000 cases glioblastoma diagnosed each year and for this reason it is considered an orphan disease. The standard of care for glioblastoma involves surgical resection or biopsy, followed by radiation/chemotherapy, and Optune therapy. The appellant underwent a biopsy in December 2015 and then initiated radiation therapy concurrent with chemotherapy for 6-12 weeks. Following the NCCN category 2A recommendations for alternating Optune with adjuvant temozolomide following standard radiation therapy, the Appellant began on Optune therapy. He completed 12 cycles of temozolomide in December of 2016, after which he continued with just the Optune treatment alone. She clarified that the standard of care is to discontinue the adjuvant chemotherapy after 12 cycles due to the toxic nature of the treatment. Chemotherapy is only reinitiated if there is confirmation of tumor progression. Ms. Miles noted that the Appellant's MRIs on May 2017, July 2017, September 2017, February 2018 and April 2018 have been stable and show no tumor progression. She also described that the quality of life for patients using the Optune treatment is far superior to standard radiation and chemotherapy because it has no toxic side effects. She stated that the only common side effect has been skin irritation at the site of the electrodes, but in this case the Appellant had tolerated the treatment without any side effects. Ms. Miles noted that the Appellant has had an exceptional outcome with the Optune treatment and that recently he has been hunting and plans to also go hiking. As stated earlier, the standard prognosis for glioblastoma patients receiving only radiation and chemotherapy is only 10 months survival. The treatment with Optune which works by providing alternating electric field pulses to the brain to interfere with the cell division of the tumor cells has revolutionized glioblastoma treatment and in the case of the Appellant had afforded him almost 3 years of survival with a very high quality of life. (Hearing CD.)

The ALJ, after thorough review of the administrative record, finds the appellant has satisfied the Medicare Part B coverage criteria for reimbursement. The treating physician's notes reflected that the beneficiary had glioblastoma multiforme. Exh. 2, pp. 109-11. Following his diagnosis on November 2, 2012, the beneficiary initially underwent biopsy and radiation and was also treated with concurrent temozolomide chemotherapy. *Id.* The record shows that he also received multiple cycles of Temodar. *Id.* At this point in his therapy, his physician recommended treatment with Optune system as the standard medical therapy for glioblastoma multiforme after surgical and radiation options had been exhausted. Exh. 2, pp. 1-3.

The medical record indicates that Optune treatment was initiated on August 3, 2016. Exh. 2, pp. 18-21. The Appellant completed adjuvant chemotherapy in December 2016, and after that period of time, he only continued with the Optune treatment. *Id.* Despite many repeated MRI's scans of his brain, the glioblastoma tumor has not grown. *Testimony.* He has already survived 34 months, more than three times the normal length of survival for such a malignant tumor of the brain. *Id.* Further, the beneficiary remains active and of full mental capacity without showing signs of slowing down or the malignant brain tumor affecting his lifestyle or abilities. *Id.*

There are many studies and reports in the medical record which show the effectiveness of the Optune device for malignant tumors of the brain (glioblastomas). I find the documentation and arguments during testimony to be persuasive and demonstrated that the device is not experimental or investigational, but like the FDA and many commercial and Medicaid programs I find the device not only to be very effective and useful for its stated uses, but to be the standard of care for glioblastoma treatment.

Therefore, I am issuing a favorable decision in this matter as I find good reason to not find the LCD controlling here based upon the circumstances of this case and the successful use of the Optune device, a FDA approved product which through numerous studies has shown not to be experimental and investigational, but has shown to be very effective in its treatment of glioblastomas.

Accordingly, coverage criteria have been met and the detailed medical records contain a letter of medical necessity from the physician with the rationale for the device in addition to the prescription and order form. Exh. 2, pp. 1-21.

Because the claim is covered by Medicare, the issue of liability is not addressed.

Conclusions of Law

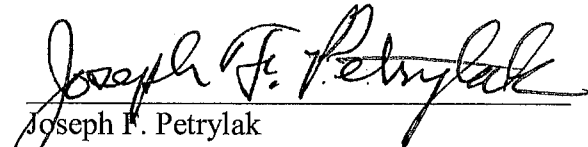
Payment may be made for the Tumor Treatment Field Therapy (TTFT) with Optune, also known as Novo-TTF 100A Plus Transducers (E0766) provided to the Appellant on August 3, 2017, September 3, 2017, and October 3, 2017.

Order

The Medicare Contractor is directed to process the claim in accordance with this decision.

SO ORDERED

Dated: 10/23/2018


Joseph F. Petrylak
Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Cleveland, Ohio

Appeal of:

REDACTED

OMHA Appeal No.: 1-7843876383

Beneficiary:

Medicare: **Part B**

Medicare No.: *****7930A

Before: **Joseph F. Petrylak**
Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, a **FAVORABLE** decision is entered for the Appellant.

Procedural History

REDACTE (hereinafter, the Appellant), submitted a claim to submitted a claim to the Medicare to be reimbursed under Medicare Part B for durable medical equipment (DME) specifically, Tumor Treatment Field Therapy (TTFT) with Novocure Novo-TTF 100A Plus Transducers (E0766) provided to the Appellant on August 23, 2017, September 23, 2017, and October 23, 2017.

The claim was initially denied by the Medicare contractor. On January 8, 2018, the Medicare Administrative Contractor upheld the denial on redetermination. Exh. 1, pp. 13-16. On August 3, 2018, the QIC issued an unfavorable reconsideration and determined that the documentation did not meet the requirements of the LCD L34823, that the medical record did not support the need for the device, and that there was insufficient medical literature to clearly demonstrate the effectiveness of the device. Exh. 1, pp. 1-5. The Supplier, Novocure, was held liable for the cost of the uncovered device. *Id.*

The Office of Medicare Hearings and Appeals received the Appellant's timely filed appeal on August 27, 2018. Exh. 3, pp. 1-7, Master CD. Claims have been consolidated as requested by the Appellant. *Id.* The amount in controversy satisfies the jurisdictional requirement for an Administrative Law Judge (ALJ) hearing pursuant to Title XVIII of the Social Security Act (Act) § 1869(b)(1)(E) and 42 C.F.R. § 405.1006.

An administrative hearing was held by telephone on January 8, 2019. The Appellant was represented by counsel, Debra M. Parrish, Esq. At the hearing, Julie Miles, RN, Novocure Clinical Specialist, testified for the Appellant. All exhibits were admitted into evidence without objection and were considered in reaching this decision.

Issue

The issue on appeal is whether payment may be made for Tumor Treatment Field Therapy (TTFT) with Optune, also known as Novo-TTF 100A Plus Transducers (E0766) provided to the Appellant on August 23, 2017, September 23, 2017, and October 23, 2017.

Findings of Fact

In May 2017, the Appellant, a 60-year-old female, experienced extreme dizziness after popping her ears. Exh. 2, pp. 22-23. She was subsequently found to have a mass centered within the left cingulate gyrus of the brain. *Id.* MRI scans of the brain showed a tumor of 2.1 x 1.9x 2.2 cm. *Id.* On May 16, 2017, the Appellant underwent a biopsy and was diagnosed with glioblastoma (Grade IV, IDH wild type). *Id.* A follow-up consult with oncology deemed that her tumor was non-operable. *Id.* The Appellant received multiple cycles of Temodar. *Id.* She also received a total of 60 Gy of radiation therapy. *Id.*

On August 10, 2017 Dr. REDACTED from the Kettering Cancer Center prescribed the use of Optune, formerly called Novo TTF-100A system for 6 months to treat the Appellant's glioblastoma, ICD-9 code C71.8. Exh. 2, pp. 71-72.

The Appellant received education and training on the use of her system on August 29, 2017. Exh. 2, pp. 17-21.

Legal Framework

I. Administrative Law Judge Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) § 1869(b)(1)(A).

In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *Id.*

A hearing before an ALJ is only available if the remaining amount in controversy is \$130 or more. *See* 42 C.F.R. § 405.720, 42 C.F.R. § 405.1002, and 42 C.F.R. § 405.1006. The request for hearing is timely if filed within sixty days after receipt of a QIC decision. *See* 42 C.F.R. § 405.722 and 42 C.F.R. § 405.1002.

B. Scope of Review

“The issues before the ALJ include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in a party's favor . . . However, if evidence presented

before the hearing causes the ALJ to question a favorable portion of the determination, he or she notifies the parties before the hearing and will consider it an issue at the hearing.” 42 C.F.R. § 405.1032.

“If the evidence in the hearing record supports a finding in favor of appellant(s) on every issue, the ALJ may issue a hearing decision without giving the parties prior notice and without holding a hearing.” 42 C.F.R. § 405.1038.

A Medicare Part A Administrative Law Judge Hearing is governed by the procedures set forth at 42 C.F.R. §§ 405.1000 through 405.1054.

C. Standard of Review

The Office of Medicare Hearings and Appeals Administrative Law Judges “conduct impartial ‘de novo’ hearings.” 70 Fed. Reg. 36386 (June 23, 2005).

II. Principles of Law

A. Statutes

Title XVIII § 1832 of the Social Security Act describes the scope of the benefits provided to beneficiaries under Medicare Part B, which includes medical and other health services. Title XVIII § 1861 provides that “medical and other health services” includes durable medical equipment and supplies.

Title XVIII § 1833(e) of the Social Security Act provides that no payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

Title XVIII § 1862(a)(1)(A) of the Social Security Act provides that, “Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services . . . which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”

Section 1879 of the Act provides that when Medicare coverage and payment is excluded pursuant to Section 1862(a)(1) or (a)(9), payment may nevertheless be made for items or services, if neither the beneficiary nor the provider or supplier knew, and could not reasonably be expected to have known, that the items or services would not be covered or payable by Medicare.

B. Policy and Guidance

CMS, Medicare Program Integrity Manual (MPIM) (Internet-Only Manual Publ’n 100-08)
Ch. 5, § 5.7, provides in pertinent part:

For any DMEPOS item to be covered by Medicare, the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the patient's diagnosis and other pertinent information including, but not limited to, duration of the patient's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc.

Local Coverage Determinations (LCDs) are developed by Medicare contractors to help determine whether certain items or services are covered. These LCDs are binding on the Medicare contractors in determining what items are covered but are not binding on ALJs. However, they are required to be given substantial deference by an ALJ and any failure to follow an LCD must be explained.

Local Coverage Determination, L34823 addresses tumor treatment field therapy (TTFT).

The LCD states:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

Analysis

On appeal, the QIC denied payment for Novocure TTF 100-A device and transducer array supplies at issue on the basis that the coverage requirements were not met. Exh. 1, pp. 4-7. Specifically the QIC stated that there was insufficient documentation to quantify the effect of the device for this Appellant, and that the medical records did not support why the Appellant needed this treatment. *Id.* The Appellant contends the documentation submitted meets coverage criteria for the Novo TTF 100-A system and transducer arrays supplies (E0766). Exh. 3, pp. 18-19. After careful review of the record, the ALJ disagrees with the QIC and finds that there is sufficient documentation to meet the requirements for Medicare payment of the Novo TTF 100-A system and transducer arrays supplies (E0766).

At hearing, Deborah Parrish, Esq. (the Appellant's attorney) and Julie Miles, RN made the following presentation: Ms. Parrish acknowledged that the QIC denied the payment for the Appellant's treatment based on three issues: the medical documentation did not quantify the effectiveness of the device; there was not sufficient medical literature to support the effectiveness of the device; and the LCD L34823 states that TTFT will be denied as not medically necessary.

She argued that the effectiveness of the TTFT is self-evident and should be quantifiable by simply counting the number of months beyond the standard 10 months of life expectancy for patients with glioblastoma. The Appellant was first diagnosed in May of 2017, but she continues to survive and is doing great. She reiterated that the device has received FDA approval and is the only example of the Data and Safety Monitoring Board to recommend early termination of clinical trials so that patients in the control arm could switch over to treatment. This decision was reached because of the unquestionable effectiveness of the device. In the scientific literature, Optune treatment results have been classified as level I evidence which indicates that the scientific community has 100% consensus on the effectiveness of the treatment. She also noted that the National Cancer Guidelines have been updated to include Optune as the recommended treatment for glioblastoma, it has been prescribed in all 50 states, and is the standard of care for glioblastoma. Third, she argues that the LCD is not controlling. It has not been updated since 2013, is very out of date, and should not be applied to cases of newly diagnosed glioblastoma. Ms. Parrish also stated that the DMAC is currently working to update the LCD to add treatment of glioblastoma as a covered use. Lastly, Ms. Parrish noted that the Medicare coding assignment of Tumor treatment field therapy (E0766) is in itself an acknowledgement that the treatment has been accepted in the medical community and was being widely used. The treatment would never have been assigned a code if it was still considered experimental. Hearing CD.

Ms. Julie Miles testified that the Appellant was diagnosed with a non-resectable brain tumor because of its location within the brain. She noted the Appellant is currently doing great and is grateful for the Optune therapy. The standard of care for glioblastoma involves surgical resection or biopsy, followed by radiation/chemotherapy, and Optune therapy. Because the Appellant's tumor is non-operable, it was not possible to surgically reduce her tumor burden. She described that one brain scan in December 2017 showed that her tumor had some progression, but since that scan and a medication change, her tumor has been stable. The treatment with Optune which works by providing alternating electric field pulses to the brain to interfere with the cell division of the tumor cells has revolutionized glioblastoma treatment and in the case of the Appellant had afforded her increased survival with a very high quality of life. The treatment will be necessary for the duration of her disease, or for as long as it remains effective in keeping the tumor from progressing. Hearing CD.

The ALJ, after thorough review of the administrative record, finds the Appellant has satisfied the Medicare Part B coverage criteria for reimbursement. The treating physician's notes reflected that the Appellant has newly diagnosed glioblastoma. Exh. 2, pp. 22-23. Following her diagnosis on May 16, 2017, the Appellant initially underwent biopsy and radiation and was also treated with concurrent chemotherapy. *Id.* At this point in her therapy, her physician recommended treatment with Optune system as the standard medical therapy for glioblastoma particularly because her tumor was inoperable. Exh. 2, pp. 1-3.

The medical record indicates that Optune treatment was initiated on August 29, 2017. Exh. 2, pp. 17-21. Despite many repeated MRI's scans of her brain, the glioblastoma tumor has not progressed in size since December 2017. *Testimony.* Further, the Appellant remains active and of full mental capacity without showing signs of slowing down or the malignant brain tumor affecting her lifestyle or abilities. *Id.*

There are many studies and reports in the medical record which show the effectiveness of the Optune device for malignant tumors of the brain (glioblastomas). I find the documentation and

arguments during testimony to be persuasive and demonstrated that the device is not experimental or investigational, but like the FDA and many commercial and Medicaid programs I find the device not only to be very effective and useful for its stated uses, but to be the standard of care for glioblastoma treatment.

Therefore, I am issuing a favorable decision in this matter as I find good reason to not find the LCD controlling here based upon the circumstances of this case and the successful use of the Optune device, a FDA approved product which through numerous studies has shown not to be experimental and investigational, but has shown to be very effective in its treatment of glioblastomas.

Accordingly, coverage criteria have been met and the detailed medical records contain a letter of medical necessity from the physician with the rationale for the device in addition to the prescription and order form. Exh. 2, pp. 1-73.

Because the claim is covered by Medicare, the issue of liability is not addressed.

Conclusions of Law


Payment may be made for the Tumor Treatment Field Therapy (TTFT) with Optune, also known as Novo-TTF 100A Plus Transducers (E0766) provided to the Appellant on August 23, 2017, September 23, 2017, and October 23, 2017.

Order

The Medicare Contractor is directed to process the claim in accordance with this decision.

SO ORDERED

Dated: 1/22/2019


Joseph F. Petrylak
Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Cleveland, Ohio

Appeal of: REDACTED

OMHA Appeal No.: 1-7901425924

Beneficiary:

Medicare: **Part B**

Medicare No.: *****7930A

Before: **Joseph F. Petrylak**
Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, a **FAVORABLE** decision is entered for the Appellant.

Procedural History

REDACTED (hereinafter, the Appellant), submitted a claim to the Medicare to be reimbursed under Medicare Part B for durable medical equipment (DME) specifically, Tumor Treatment Field Therapy (TTFT) with Novocure Novo-TTF 100A Plus Transducers (E0766) provided to the Appellant on November 23, 2017, December 23, 2017, and January 23, 2018.

The claim was initially denied by the Medicare contractor. On March 23, 2018, the Medicare Administrative Contractor upheld the denial on redetermination. Exh. 1, pp. 14-16. On August 17, 2018, the QIC issued an unfavorable reconsideration and determined that the documentation did not meet the requirements of the LCD L34823, that the medical record did not support the need for the device, and that there was insufficient medical literature to clearly demonstrate the effectiveness of the device. Exh. 1, pp. 1-5. The Supplier, Novocure, was held liable for the cost of the uncovered device. *Id.*

The Office of Medicare Hearings and Appeals received the Appellant's timely filed appeal on October 9, 2018. Exh. 4, pp. 1-28, Master CD. Claims have been consolidated as requested by the Appellant. *Id.* The amount in controversy satisfies the jurisdictional requirement for an Administrative Law Judge (ALJ) hearing pursuant to Title XVIII of the Social Security Act (Act) § 1869(b)(1)(E) and 42 C.F.R. § 405.1006.

An administrative hearing was held by telephone on January 8, 2019. The Appellant was represented by counsel, Debra M. Parrish, Esq. At the hearing, Julie Miles, RN, Novocure Clinical Specialist, testified for the Appellant. All exhibits were admitted into evidence without objection and were considered in reaching this decision.

Issue

The issue on appeal is whether payment may be made for Tumor Treatment Field Therapy (TTFT) with Optune, also known as Novo-TTF 100A Plus Transducers (E0766) provided to the Appellant on November 23, 2017, December 23, 2017, and January 23, 2018.

Findings of Fact

In May 2017, the Appellant, a 60-year-old female, experienced extreme dizziness after popping her ears. Exh. 2, pp. 22-23. She was subsequently found to have a mass centered within the left cingulate gyrus of the brain. *Id.* MRI scans of the brain showed a tumor of 2.1 x 1.9x 2.2 cm. *Id.* On May 16, 2017, the Appellant underwent a biopsy and was diagnosed with glioblastoma (Grade IV, IDH wild type). *Id.* A follow-up consult with oncology deemed that her tumor was non-operable. *Id.* The Appellant received multiple cycles of Temodar. *Id.* She also received a total of 60 Gy of radiation therapy. *Id.*

On August 10, 2017 Dr. REDACTED from the Kettering Cancer Center prescribed the use of Optune, formerly called Novo TTF-100A system for 6 months to treat the Appellant's glioblastoma, ICD-9 code C71.8. Exh. 2, pp. 71-72.

The Appellant received education and training on the use of her system on August 29, 2017. Exh. 2, pp. 17-21.

Legal Framework

I. Administrative Law Judge Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) § 1869(b)(1)(A).

In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *Id.*

A hearing before an ALJ is only available if the remaining amount in controversy is \$130 or more. *See* 42 C.F.R. § 405.720, 42 C.F.R. § 405.1002, and 42 C.F.R. § 405.1006. The request for hearing is timely if filed within sixty days after receipt of a QIC decision. *See* 42 C.F.R. § 405.722 and 42 C.F.R. § 405.1002.

B. Scope of Review

"The issues before the ALJ include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in a party's favor . . . However, if evidence presented

before the hearing causes the ALJ to question a favorable portion of the determination, he or she notifies the parties before the hearing and will consider it an issue at the hearing.” 42 C.F.R. § 405.1032.

“If the evidence in the hearing record supports a finding in favor of appellant(s) on every issue, the ALJ may issue a hearing decision without giving the parties prior notice and without holding a hearing.” 42 C.F.R. § 405.1038.

A Medicare Part A Administrative Law Judge Hearing is governed by the procedures set forth at 42 C.F.R. §§ 405.1000 through 405.1054.

C. Standard of Review

The Office of Medicare Hearings and Appeals Administrative Law Judges “conduct impartial ‘de novo’ hearings.” 70 Fed. Reg. 36386 (June 23, 2005).

II. Principles of Law

A. Statutes

Title XVIII § 1832 of the Social Security Act describes the scope of the benefits provided to beneficiaries under Medicare Part B, which includes medical and other health services. Title XVIII § 1861 provides that “medical and other health services” includes durable medical equipment and supplies.

Title XVIII § 1833(e) of the Social Security Act provides that no payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

Title XVIII § 1862(a)(1)(A) of the Social Security Act provides that, “Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services . . . which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”

Section 1879 of the Act provides that when Medicare coverage and payment is excluded pursuant to Section 1862(a)(1) or (a)(9), payment may nevertheless be made for items or services, if neither the beneficiary nor the provider or supplier knew, and could not reasonably be expected to have known, that the items or services would not be covered or payable by Medicare.

B. Policy and Guidance

CMS, *Medicare Program Integrity Manual (MPIM) (Internet-Only Manual Publ’n 100-08)*
Ch. 5, § 5.7, provides in pertinent part:

For any DMEPOS item to be covered by Medicare, the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the patient's diagnosis and other pertinent information including, but not limited to, duration of the patient's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc.

Local Coverage Determinations (LCDs) are developed by Medicare contractors to help determine whether certain items or services are covered. These LCDs are binding on the Medicare contractors in determining what items are covered but are not binding on ALJs. However, they are required to be given substantial deference by an ALJ and any failure to follow an LCD must be explained.

Local Coverage Determination, L34823 addresses tumor treatment field therapy (TTFT).

The LCD states:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

Analysis

On appeal, the QIC denied payment for Novocure TTF 100-A device and transducer array supplies at issue on the basis that the coverage requirements were not met. Exh. 1, pp. 4-7. Specifically the QIC stated that there was insufficient documentation to quantify the effect of the device for this Appellant, and that the medical records did not support why the Appellant needed this treatment. *Id.* The Appellant contends the documentation submitted meets coverage criteria for the Novo TTF 100-A system and transducer arrays supplies (E0766). Exh. 3, pp. 18-19. After careful review of the record, the ALJ disagrees with the QIC and finds that there is sufficient documentation to meet the requirements for Medicare payment of the Novo TTF 100-A system and transducer arrays supplies (E0766).

At hearing, Deborah Parrish, Esq. (the Appellant's attorney) and Julie Miles, RN made the following presentation: Ms. Parrish acknowledged that the QIC denied the payment for the Appellant's treatment based on three issues: the medical documentation did not quantify the effectiveness of the device; there was not sufficient medical literature to support the effectiveness of the device; and the LCD L34823 states that TTFT will be denied as not medically necessary.

She argued that the effectiveness of the TTFT is self-evident and should be quantifiable by simply counting the number of months beyond the standard 10 months of life expectancy for patients with glioblastoma. The Appellant was first diagnosed in May of 2017, but she continues to survive and is doing great. She reiterated that the device has received FDA approval and is the only example of the Data and Safety Monitoring Board to recommend early termination of clinical trials so that patients in the control arm could switch over to treatment. This decision was reached because of the unquestionable effectiveness of the device. In the scientific literature, Optune treatment results have been classified as level I evidence which indicates that the scientific community has 100% consensus on the effectiveness of the treatment. She also noted that the National Cancer Guidelines have been updated to include Optune as the recommended treatment for glioblastoma, it has been prescribed in all 50 states, and is the standard of care for glioblastoma. Third, she argues that the LCD is not controlling. It has not been updated since 2013, is very out of date, and should not be applied to cases of newly diagnosed glioblastoma. Ms. Parrish also stated that the DMAC is currently working to update the LCD to add treatment of glioblastoma as a covered use. Lastly, Ms. Parrish noted that the Medicare coding assignment of Tumor treatment field therapy (E0766) is in itself an acknowledgement that the treatment has been accepted in the medical community and was being widely used. The treatment would never have been assigned a code if it was still considered experimental. Hearing CD.

Ms. Julie Miles testified that the Appellant was diagnosed with a non-resectable brain tumor because of its location within the brain. She noted the Appellant is currently doing great and is grateful for the Optune therapy. The standard of care for glioblastoma involves surgical resection or biopsy, followed by radiation/chemotherapy, and Optune therapy. Because the Appellant's tumor is non-operable, it was not possible to surgically reduce her tumor burden. She described that one brain scan in December 2017 showed that her tumor had some progression, but since that scan and a medication change, her tumor has been stable. The treatment with Optune which works by providing alternating electric field pulses to the brain to interfere with the cell division of the tumor cells has revolutionized glioblastoma treatment and in the case of the Appellant had afforded her increased survival with a very high quality of life. The treatment will be necessary for the duration of her disease, or for as long as it remains effective in keeping the tumor from progressing. Hearing CD.

The ALJ, after thorough review of the administrative record, finds the Appellant has satisfied the Medicare Part B coverage criteria for reimbursement. The treating physician's notes reflected that the Appellant has newly diagnosed glioblastoma. Exh. 2, pp. 22-23. Following her diagnosis on May 16, 2017, the Appellant initially underwent biopsy and radiation and was also treated with concurrent chemotherapy. *Id.* At this point in her therapy, her physician recommended treatment with Optune system as the standard medical therapy for glioblastoma particularly because her tumor was inoperable. Exh. 2, pp. 1-3.

The medical record indicates that Optune treatment was initiated on August 29, 2017. Exh. 2, pp. 17-21. Despite many repeated MRI's scans of her brain, the glioblastoma tumor has not progressed in size since December 2017. *Testimony.* Further, the Appellant remains active and of full mental capacity without showing signs of slowing down or the malignant brain tumor affecting her lifestyle or abilities. *Id.*

There are many studies and reports in the medical record which show the effectiveness of the Optune device for malignant tumors of the brain (glioblastomas). I find the documentation and

arguments during testimony to be persuasive and demonstrated that the device is not experimental or investigational, but like the FDA and many commercial and Medicaid programs I find the device not only to be very effective and useful for its stated uses, but to be the standard of care for glioblastoma treatment.

Therefore, I am issuing a favorable decision in this matter as I find good reason to not find the LCD controlling here based upon the circumstances of this case and the successful use of the Optune device, a FDA approved product which through numerous studies has shown not to be experimental and investigational, but has shown to be very effective in its treatment of glioblastomas.

Accordingly, coverage criteria have been met and the detailed medical records contain a letter of medical necessity from the physician with the rationale for the device in addition to the prescription and order form. Exh. 2, pp. 1-73.

Because the claim is covered by Medicare, the issue of liability is not addressed.

Conclusions of Law

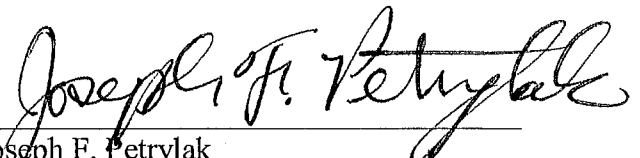
Payment may be made for the Tumor Treatment Field Therapy (TTFT) with Optune, also known as Novo-TTF 100A Plus Transducers (E0766) provided to the Appellant on November 23, 2017, December 23, 2017, and January 23, 2018.

Order

The Medicare Contractor is directed to process the claim in accordance with this decision.

SO ORDERED

Dated: 1/22/2018



Joseph F. Petrylak
Administrative Law Judge



**Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City, Missouri**

Appeal of:	OMHA Appeal No.: 1-7737796930
Beneficiary:	Medicare: Part B
Medicare No.:	Before: James Plott Administrative Law Judge

DECISION

After careful consideration of all the evidence and arguments presented in the hearing and record, this Administrative Law Judge (ALJ) enters a **FULLY FAVORABLE** decision for the Appellant/Beneficiary, The electrical stimulation device for cancer treatment (E0766) is covered for the dates of service of 07/06/2017, 08/09/2017, and 09/06/2017.

Procedural History

The Medicare Administrative Contractor denied payment for the device initially and after redetermination. The Appellant requested reconsideration from a Qualified Independent Contractor (QIC), which issued an unfavorable decision on June 13, 2018. (Exh. 1, p. 1).

The Appellant filed a request for hearing before an ALJ, which was received by the Office of Medicare Hearings and Appeals (OMHA) on August 2, 2018. (Exh. 5, p. 1).

Jurisdiction is proper as the request was timely and the amount in controversy meets the jurisdictional requirements for an ALJ hearing. *See* 42 C.F.R. §§ 405.1000(d), 405.1002(a)(1), 405.1006(b)(1).

A hearing on this matter was held by telephone on September 19, 2018. (Exh. 6, p. 1). Debra Parrish, Esq. appeared as the designated representative for the Beneficiary. Justin Kelly, R.N., appeared and testified on behalf of the Beneficiary. (Hearing CD). Exhibits 1 through 7 were admitted into evidence without objection. (Hearing CD). At the conclusion of the argument and testimony, the record was closed and the hearing was concluded.

Issues

The issues before the ALJ include all of the issues brought out in the initial determination, coverage determination, or organization determination; redetermination; or

reconsideration that were not decided entirely in a party's favor, for the claims or other appealed matters specified in the request for hearing.

Findings of Fact

1. The Beneficiary was 69 years old on the dates of service at issue. He had a bi-frontal glioblastoma multiforme (GBM) resected in January 2014 with pathology consistent with a World Health Organization (WHO) grade IV GBM. The bi-frontal GBM is in the frontal lobe and is a supratentorial GBM. For the dates of service at issue, the Beneficiary was still receiving treatment for the newly diagnosed GBM and was not receiving treatment for a recurrent GBM. He completed concurrent radiotherapy and chemotherapy and 12 post adjuvant cycles of temozolomide. He was prescribed and using the Optune System (formerly known as NovoTTF system), which delivers alternating electrical fields of Tumor Treating Fields (TTF) to the brain¹. (Exh. 4, pp. 3-4, 23-30; Hearing CD).

2. GBM is an aggressive, malignant, primary brain tumor. Survival at initial presentation is approximately 10 months, even with aggressive chemotherapy. Because it is extremely rare for GBM to metastasize, it is efficient to treat the disease with regional therapy as part of the treatment strategy. (Exh. 3, pp. 7-19; Exh. 5, p. 2 (citing Rulsch et al. "Long-term survival of patients suffering from glioblastoma multiforme treated with tumor-treating fields." World Journal of Surgical Oncology at 1); Exh. 7, p. 2).

3. A large body of peer-reviewed literature shows that tumor treating fields, also known as alternating electric fields, disrupt the cell division process in cancerous tumors which may lead to programmed cell death or apoptosis. Tumor treating fields have shown statistically significant improvement in patient survival and outcomes in glioblastoma multiforme (GBM) brain tumors compared with traditional standard of care alone. (Exh. 2, Sworn Declaration of Justin Kelly, Optune Peer Reviewed Literature).

4. Novocure's Optune device was FDA-approved through the Premarket Approval (PMA) pathway for the treatment of adult patients with recurrent glioblastoma in April 2011. In 2015, the FDA-approved the Optune device for the treatment of adults with newly diagnosed glioblastoma in combination with temozolomide chemotherapy after completing radiation therapy. (Exh. 2, Sworn Declaration of Justin Kelly, Optune FDA PMA P100034, Optune FDA PMA P100034S0134A).

5. Since the Optune device was FDA-approved, more than 800 leading oncology centers throughout the United States have been certified to provide and prescribe Optune. (Exh. 2, Sworn Declaration of Justin Kelly).

6. Optune has been prescribed by more than 1200 providers in all 50 states, Puerto Rico and the District of Columbia. As of July 18, 2018, the Optune device has been prescribed for over 7200 patients in the United States. (Exh. 2, Sworn Declaration of Justin Kelly).

7. The Optune device and its clinical effectiveness have been described in over 140 peer reviewed publications. (Exh. 2, Sworn Declaration of Justin Kelly, Optune Peer Reviewed Literature).

¹ TTF therapy is commonly referred to as TTFT.

8. The Optune device has been accepted by the relevant clinical community as a treatment to improve the clinical outcomes and extend the survival of patients diagnosed with a glioblastoma. (Exh. 2, Sworn Declaration of Justin Kelly).

9. More than 35 commercial payers, including virtually all the large national payers, deem Optune to be reasonable and medically necessary for beneficiaries diagnosed with a glioblastoma, and provide coverage for the device through published coverage policy. (Exh. 2, Sworn Declaration of Justin Kelly, Optune Medical Policies July 2018).

10. Several Medicaid states have adopted positive coverage policies for Optune. (Exh. 2, Sworn Declaration of Justin Kelly).

11. On August 7, 2018, the Administrative Contractor issued a letter concerning Novocure's request for formal reconsideration of the TTFT Local Coverage Determination (LCD). The Administrative Contractor noted at that time that "[c]urrently, the TTFT LCD includes language indicating that the coverage of TTFT for recurrent glioblastoma multiforme (GBM) is not reasonable and necessary. Coverage of newly diagnosed GBM is not addressed." The Administrative Contractor considered Novocure's request to revise the LCD to provide for coverage of TTFT for the treatment of adult patients with newly diagnosed supratentorial GBM to be valid request due to the submission of new evidence supporting the request. These studies included:

Stupp R, Taillibert S, Kanner AA, et al. *Maintenance therapy with tumor-treating fields plus temozolomide vs temozolomide alone for glioblastoma: a randomized clinical trial*. JAMA. 2015;314(23):2535-2543.

Stupp R, Taillibert S, Kanner A, et al. *Effect of Tumor-Treating Fields Plus Maintenance Temozolomide vs Maintenance Temozolomide Alone on Survival in Patients With Glioblastoma A Randomized Clinical Trial*. JAMA. 2017;318(23):2306-2316. doi:10.1001/jama.2017.18718

Taphoorn MJB, Dirven L, Kanner AA, Lavy-Shahaf G, Weinberg U, Taillibert S, Toms SA, Honnorat J, Chen TC, Sroubek J, David C, Idhah A, Easaw JC, Kim CY, Bruna J, Hottinger AF, Kew Y, Roth P, Desai R, Villano JL, Kirson ED, Ram Z, Stupp R. *Influence of Treatment With Tumor-Treating Fields on Health-Related Quality of Life of Patients With Newly Diagnosed Glioblastoma: A Secondary Analysis of a Randomized Clinical Trial*. JAMA Oncol. 2018 Apr 1;4(4):495-504. doi: 10.1001/jamaoncol.2017.5082.

(Exh. 7, pp. 10-12).

12. The Journal of the American Medical Association (JAMA) published a study of maintenance therapy for newly-diagnosed glioblastoma with tumor-treating fields plus temozolomide versus temozolomide alone on December 15, 2015. (R. Stupp, et al, *Maintenance Therapy with Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma: A Randomized Clinical Trial*, 314 Journal of the American Medical Association 2535 (2015)). The controlled, randomized trial with 695 patients concluded that progression-free

survival and overall survival were greater among the patients receiving both tumor treating fields and temozolomide than for patients receiving only temozolomide. Based on the interim analysis of the trial, the study was concluded early. The interim analysis showed that adding tumor treatment fields to temozolomide thermotherapy “significantly prolonged progression-free and overall survival.” (Exh. 4, pp. 35-45).

13. JAMA published a study of whether TTFields improves progression-free and overall survival of patients with GBM on December 19, 2015. (Stupp R, Taillibert S, Kanner A, et al. *Effect of Tumor-Treating Fields Plus Maintenance Temozolomide vs Maintenance Temozolomide Alone on Survival in Patients With Glioblastoma A Randomized Clinical Trial*. JAMA. 2017;318(23):2306-2316. doi:10.1001/jama.2017.18718). The study concluded:

In the final analysis of this randomized clinical trial of patients with glioblastoma who had received standard radiochemotherapy, the addition of TTFields to maintenance temozolomide chemotherapy vs maintenance temozolomide alone, resulted in statistically significant improvement in progression-free survival and overall survival. These results are consistent with the previous interim analysis.

(Exh. 2).

14. JAMA published a study examining the association of TTFields therapy with progression-free survival and HRQoL among patients with glioblastoma on February 1, 2018. Taphoorn MJB, Dirven L, Kanner AA, Lavy-Shahaf G, Weinberg U, Taillibert S, Toms SA, Honnorat J, Chen TC, Sroubek J, David C, Idhah A, Easaw JC, Kim CY, Bruna J, Hottinger AF, Kew Y, Roth P, Desai R, Villano JL, Kirson ED, Ram Z, Stupp R. *Influence of Treatment With Tumor-Treating Fields on Health-Related Quality of Life of Patients With Newly Diagnosed Glioblastoma: A Secondary Analysis of a Randomized Clinical Trial*. JAMA Oncol. 2018 Apr 1;4(4):495-504. doi: 10.1001/jamaoncol.2017.5082. The study concluded:

The addition of TTFields to standard treatment with temozolomide for patients with glioblastoma results in improved survival without a negative influence on HRQoL except for more itchy skin, an expected consequence from the transducer arrays.

(Exh. 2).

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual or an organization who is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. 42 C.F.R. § 405.1002; the Act § 1869(b)(1)(A). In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. 70 Fed. Reg. 36386, 36387

(June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary unless later reviewed by the Medicare Appeals Council. *Id.*

The minimum amount in controversy required for a request for an ALJ hearing filed in 2014 is \$140. Act § 1869(b)(1)(E); 42 C.F.R. § 405.1006(d)(1)(ii); 78 Fed. Reg. 59702 (Sept. 27, 2013).

In this case, the Appellant timely requested a hearing before an ALJ. 42 C.F.R. § 405.1014. And the remaining amount in controversy meets the jurisdictional requirements for a hearing. 42 C.F.R. § 405.1006.

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in a party's favor. 42 C.F.R. § 405.1032. However, if evidence presented before or during the hearing causes the ALJ to question a fully favorable decision, he or she will notify the Appellant and will consider it an issue at the hearing. *Id.*

An ALJ may issue a decision on the record on his or her own initiative if the evidence in the hearing record supports a fully favorable finding. 42 C.F.R. §§ 405.1000(g) and 405.1038(a). In addition, if all parties to the hearing waive their right to appear at the hearing, the ALJ may make a decision based on the evidence that is in the record and any new evidence that is admitted by the ALJ. 42 C.F.R. §§ 405.1000(e) and 405.1038(b)(1)(i).

C. Standard of Review

The ALJ conducts a de novo review of each claim at issue. 42 C.F.R. § 405.1000(d); *see also* Administrative Procedures Act, 5 U.S.C. § 557. A de novo review requires the ALJ to review and evaluate the evidence without regard to the findings in the prior determinations on the claim and make an independent assessment in reliance upon the evidence and controlling laws.

All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Act and applicable implementing regulations, are binding on the ALJ. 42 C.F.R. § 405.1063. National coverage determinations issued by the Secretary are also binding. 42 C.F.R. § 405.1060. ALJs and attorney adjudicators "are not bound by [local coverage determinations (LCDs)], [local medical review policies (LMRPs)], or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. § 405.1062.

The Appellant has the burden of proving entitlement to Medicare payments (satisfied through the submission of sufficient evidence in accordance with Medicare rules). *See* Administrative Procedure Act, 5 U.S.C. § 556(d); *see also* Act §§ 1814(a)(1), 1815(a) and 1833(e), and 42 C.F.R. § 424.5(a)(6) (requiring Medicare claims to be adequately supported).

II. Principles of Law

The Supplementary Medical Insurance program (Part B of Title XVIII of the Act) provides coverage for a variety of medical services and supplies furnished by physicians, or by others, in connection with physicians' services, for outpatient hospital services, and for a number of other specific health-related items and services including durable medical equipment. *See* Act §§ 1831, 1832; *see also* 42 C.F.R. § 410.10.

But notwithstanding any other provision of Title XVIII, no payment may be made under part A or part B for any expenses incurred for items or services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” Act § 1862(a)(1).

In addition to the statutes and regulation, the Administrative Contractor with jurisdiction over the claim has issued a Local Coverage determination stating that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. CGS Administrators, LLC, Local Coverage Determination L34823: Tumor Treatment Field Therapy (LCD L34823) (Jan. 2017). The related Policy Article, however, states that tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit and must meet the reasonable and necessary requirements set out in the related LCD to be eligible for reimbursement. CGS Administrators, LLC, Local Coverage Article for Tumor Treatment Field Therapy Article A52711 (Article A52711) (Jan. 2017).

The Medicare Program Integrity Manual (CMS Pub. 100-08) (MPIM), ch. 13 § 13.5.1, and the Medicare Benefit Policy Manual (CMS Pub. 100-02) (MBPM), ch. 15 § 110, provide guidance for determining whether a device is reasonable and necessary. These manuals suggest that a device is not reasonable and necessary if it is:

- Not “safe” and “effective” – that is, if the device has not been “proven safe and effective based on authoritative evidence” or is not “generally accepted in the medical community as safe and effective for the condition for which it is used.”
- “Experimental” – that is, “investigational”;
- Not “[a]ppropriate” for the individual beneficiary’s needs; or
- “[S]ubstantially more costly than a medically appropriate and realistically feasible alternative pattern of care.”

See also Almy v. Sebelius, 679 F.3d 297, 299 (4th Cir. 2012). The claimant has the burden to show that the device is reasonable and necessary. *Almy*, 679 F.3d at 305.

Medicare also instructs contractors as to the type of evidence to be used in making these technical determinations. Such decisions should be based on either “published authoritative evidence” such as “definitive randomized clinical trials” or “general acceptance by the medical community,” with the caveat that “[a]cceptance by individual health care providers” and “limited case studies distributed by sponsors with a financial interest in the outcome[] are not sufficient evidence of general acceptance by the medical community.” MPIM § 13.7.1; *see also Almy*, 679 F.3d at 300.

Analysis

This ALJ conducted a *de novo* review of the evidence to determine whether the Beneficiary established the requirements for Medicare coverage. The Beneficiary's request for an ALJ hearing was timely and satisfied jurisdictional requirements. And the tumor treatment field therapy for treatment of the Beneficiary's glioblastoma for the dates of service was medically reasonable and necessary.

In this case, there is no LCD that is currently applicable to the use of TTFT treatment for newly diagnosed GBM. As recognized by the Administrative Contractor, LCD L34823 precludes coverage of TTFT for recurrent glioblastoma multiforme (GBM) as not reasonable and necessary, but does not address coverage for newly diagnosed GBM. (Exh. 2, p. 10). And there is new evidence supporting coverage for TTFT treatment for newly diagnosed GBM, including studies published in 2015, 2017 and 2018. (Exh. 2, p. 10).

The Optune device at issue received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011. On October 5, 2015, the FDA gave premarket approval for use of Optune in patients with newly diagnosed glioblastoma. While FDA premarket approval does not establish that the device is medically reasonable and necessary pursuant to Medicare requirements, it does ensure that the FDA has closely examined the device and its application. In this case, the FDA determined that sufficient scientific evidence existed to provide the FDA with assurance that the device was safe and effective for its intended use both in patients with recurrent and newly diagnosed glioblastoma. From this perspective, the use of the device meets Medicare guidance requiring that a device be proven safe and effective based on authoritative evidence.

Second, peer-reviewed literature shows that tumor treating fields disrupt the cell division process in cancerous tumors which may lead to programmed cell death or apoptosis. Tumor treating fields have shown statistically significant improvement in patient survival and outcomes in GBM brain tumors compared with traditional standard of care alone. And the Optune device and its clinical effectiveness have been described in over 140 peer reviewed publications. These trials showed that the Optune device is safe, non-investigational and effective. In addition, these trials showed that the Optune device was appropriate for the Beneficiary's needs.

Third, the use of TTFT for treatment of GBM is generally accepted by the medical community. Since the Optune device was FDA-approved, more than 800 leading oncology centers throughout the United States have been certified to provide and prescribe Optune. Optune has been prescribed by more than 1200 providers in all 50 states, Puerto Rico and the District of Columbia. As of July 18, 2018, the Optune device has been prescribed for over 7200 patients in the United States. More than 35 commercial payers, including virtually all the large national payers, deem Optune to be reasonable and medically necessary for beneficiaries diagnosed with a glioblastoma, and provide coverage for the device through published coverage policy. And several Medicaid states have adopted positive coverage policies for Optune.

And with respect to this case, a review of the medical records and hearing demonstrated that the Beneficiary was receiving treatment for a newly diagnosed supratentorial GBM, had already undergone surgical resection of the tumor and chemotherapy, and was continuing with TTFT. As a result, the Beneficiary has greatly exceeded the typical life expectancy following a

GBM diagnosis. The preponderance of the evidence is that the TTFT was medically reasonable and necessary for the treatment of the Beneficiary's condition.

The Optune device for TTFT has been shown to be safe and effective and was medically reasonable and necessary for the treatment of this Beneficiary's condition for the dates of service in question.

Conclusions of Law

This decision is **FULLY FAVORABLE**. The Optune device using tumor treatment field therapy (TTFT) was reasonable and necessary and is covered by Medicare.


Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated:

SEP 26 2018


James Plott
Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City, Missouri

Appeal of:	OMHA Appeal No.: 1-7824751206
Beneficiary:	Medicare: Part B
Medicare No.:	Before: James Plott Administrative Law Judge

DECISION

After carefully considering the evidence in the record, the Administrative Law Judge (“ALJ”) enters a **FULLY FAVORABLE** decision for (“Appellant/Beneficiary”).

PROCEDURAL HISTORY

The Beneficiary submitted a claim to Medicare for electrical stimulation cancer treatment (E0766) for the dates of service of September 8, 2017, October 8, 2017, and November 8, 2017. Initially and upon redetermination review, the Medicare Administrative Contractor (“Contractor”) denied the claim. On July 11, 2018, C2C Innovative Solutions, Inc., a Medicare Qualified Independent Contractor (“QIC”), denied the claim upon reconsideration review.

On August 22, 2018, the Office of Medicare Hearings and Appeals (“OMHA”) received the Beneficiary’s timely request for an Administrative Law Judge (“ALJ”) hearing. On September 4, 2018, the OMHA Kansas City Field Office received a pre-hearing brief, which was admitted into the record as Exhibit 7. A hearing was held by telephone on September 19, 2018, before ALJ James Plott. All exhibits were admitted into the record. The record is now closed.

ISSUES

All issues for the claims or appealed matter specified in the request for hearing that were brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party’s favor.

FINDINGS OF FACT

1. On February 25, 2017, an MRI was performed on the Beneficiary, a 68 year-old female, revealing a lesion that was worrisome to the physicians for a Central Nervous System glioma, following episodes of involuntary movement. (Exh. 4, pp. 18–21).

2. The March 10, 2017 progress note indicates that the Beneficiary underwent a right frontal craniotomy with partial resection of the right frontal mass on March 3, 2017. The surgical pathology report confirmed the diagnosis of GBM. The treatment plan included radiation, chemotherapy, Gamma knife surgery, and the Optune device. (Exh. 4, pp. 18–21).
3. Approximately one month after the resection, specifically April 4, 2017, Gamma knife surgery was performed. The procedure note indicates that the Beneficiary thereafter resumed her fractionated radiation course. (Exh. 4, pp. 18–21).
4. Justin Kelly, Regional Vice President of Health Policy for the supplier of the Optune device, testified that the patient was prescribed the Optune device in June 2017 following these numerous other treatments. The clinician prescribed Optune for the Beneficiary as a newly diagnosed GBM patient. (Hearing CD).
5. Mr. Kelly testified at the hearing that the beneficiary's GBM progressed, representing clinical recurrence in August 2017. (Hearing CD).
6. Much like patients in the ET-14 study, the Beneficiary's clinician prescribed the device when the Beneficiary was newly diagnosed with a glioblastoma. The Beneficiary did experience progression of her disease while using the Optune, such as other patients who participated in and remained in the ET-14 study per the protocol. The Beneficiary's clinical treatment circumstances mirror those of the ET-14 study, given her continued use of the Optune system that was originally prescribed when newly diagnosed. (Hearing CD; Exh. 2, pp. 16–21).
7. Optune is FDA-approved for recurrent and newly diagnosed GBM brain tumors. (Hearing CD; Exh. 4, p 65).
8. Glioblastoma is the most common form of primary brain cancer but is still very rare (~10,000 cases annually in the U.S.). The NIH designates GBM as a rare disease, with few treatment options. GBM tumors are typically highly aggressive. (Exhs. 4, pp. 76–77; 7, p. 2); *See also* <https://rarediseases.info.nih.gov/diseases/2491/glioblastoma>).
9. The Optune system has been certified at more than 800 cancer treatment centers, and has been prescribed by over 1200 physicians in 50 states, the District of Columbia, and Puerto Rico, for over 7200 patients for treatment of GBM. (Exh. 7, pp. 3–4).
10. Virtually every major commercial payer in the United States covers the Optune system for individuals diagnosed with a glioblastoma. Policies in the record reflect coverage from payers such as Highmark, Aetna, Anthem, Humana, Kaiser, UnitedHealthcare, Cigna, Harvard Pilgrim, Geisinger, HealthPartners, and several Blue Cross plans. (Exh. 7, p. 3).
11. After being diagnosed with recurrent GBM, average overall survival is approximately 6 months from the time of recurrence without additional effective treatment.¹ Survival at

¹ Rulseh et al. "Long-term survival of patients suffering from glioblastoma multiforme treated with tumor-treating fields." *World Journal of Surgical Oncology* at 1 (2012).

initial presentation is approximately 10 months, even with aggressive chemotherapy.² (Exh. 7, p. 2).

12. "Recurrent" GBM occurs when the tumor recurs or progresses after initial treatment. Recurrent GBM is an end-stage condition. When GBM recurs, patients are rarely eligible for re-operation. As a result, patients with recurrent GBM face severely limited treatment options. (Exh. 7, p. 2).
13. The NCCN Clinical Practice Guidelines 2016 and 2017 for "Central Nervous System Cancers," include Tumor Treatment Field Therapy (TTFT) treatment for recurrent glioblastoma. (Exh. 7, p. 2).
14. A letter from the DMAC medical directors in the record, in response to an LCD reconsideration request, indicates that they do not believe the non-coverage LCD L34823 addresses instances of newly diagnosed glioblastoma. (Exh. 7, p. 4).
15. The ET-14 study (Stupp) included patients who were newly diagnosed with glioblastoma upon initial presentation. While some patients experienced a recurrence during the study, they continued to be treated with the device per the study protocol. Therefore, the study on newly diagnosed glioblastoma reflected the effectiveness of the treatment on individuals who received the device when newly diagnosed, and those who continued using it during unfortunate recurrences. The results reflected statistically significant improvement in overall survival for patients diagnosed with glioblastoma generally. (Exh. 7, p. 3).
16. Specifically, the final analysis of the randomized phase 3 trial (695 patients) found that the addition of Optune for newly diagnosed cases, in addition to those who began the study as newly diagnosed patients but suffered recurrences, to standard chemotherapy treatment "resulted in statistically significant improvement in progression-free survival and overall survival" over patients that were treated with chemotherapy alone. Stupp et al. at 2315 (JAMA 2017). See also, interim analysis of 315 patients from this study (adding Optune to maintenance chemotherapy "significantly prolonged progression-free and overall survival"). Stupp et al. at 2542 (JAMA 2015). (Exh. 7, p. 3).
17. The ET-14 study for the device at issue was deemed to have met its primary endpoints prior to its completion by the FDA and ended early, upon the recommendation of the trial's independent data monitoring committee, so as to provide the patients who were not receiving care with Optune the opportunity to receive such treatment. (Exh. 7, p. 5).

² *Id.*

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

An individual or an organization who is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services ("HHS") provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. 42 C.F.R. § 405.1014; Social Security Act ("Act") § 1869(b)(1)(A). In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary unless later reviewed by the Medicare Appeals Council. *Id.*

For requests filed in calendar year 2018, the minimum amount remaining in controversy required for an ALJ hearing is \$160.00 (following application of any co-insurance or deductible). Act § 1869(b)(1)(E); 79 Fed. Reg. 57934 (Sept. 26, 2014); 42 C.F.R. §§ 405.1006(b), 405.1006(d)(1)(ii).

To be considered timely, the request for hearing must be received by OMHA within sixty days after the Appellant receives the QIC's reconsideration decision. The Appellant is presumed to have received the QIC's reconsideration five days after the date noted on the first page of the reconsideration unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3).

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in the Appellant's favor. 42 C.F.R. § 405.1032. However, if evidence presented before or during the hearing causes the ALJ to question a fully favorable decision, he or she will notify the Appellant and will consider it an issue at the hearing. *Id.*

An ALJ may issue a decision on the record on his or her own initiative if the evidence in the hearing record supports a fully favorable finding. 42 C.F.R. §§ 405.1000(g), 1038(a). In addition, if all parties to the hearing waive their right to appear at the hearing, the ALJ may make a decision based on the evidence that is in the record and any new evidence that is admitted by the ALJ. 42 C.F.R. § 405.1000(e).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue. 42 C.F.R. § 405.1000(d) and Section 557 of the Administrative Procedures Act. A *de novo* review requires the ALJ to review and evaluate the evidence without regard to the findings in the prior determinations on the claim and make an independent assessment in reliance upon the evidence and controlling laws. All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Act and applicable implementing regulations, are binding on the ALJ. 42 C.F.R. § 405.1063.

The Appellant has the burden of proving each element of a Medicare claim by a preponderance of the evidence (satisfied through the submission of sufficient evidence in accordance with Medicare rules). *See* Act §§ 1814(a)(1), 1815(b), 1833(e); 42 C.F.R. §§ 424.5(a)(6), 405.1018, 405.1028, 405.1030.

II. Principles of Law

A. Statutes and Regulations

The statutory authority for the Medicare program is found in Title XVIII of the Act. 42 U.S.C. § 1395 *et seq.* The Supplementary Medical Insurance program (Part B of Title XVIII of the Act) provides coverage for a variety of medical services and supplies furnished by physicians, or by others in connection with physicians' services, for outpatient hospital services, and for a number of other specific health-related items and services. *See* Act § 1832; *see also* 42 C.F.R. § 410.10. The Secretary of HHS has authority to promulgate regulations which define or clarify the provisions of the Act. Those regulations are generally found at 42 C.F.R. § 410, and other provisions.

B. Medicare Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than an National Coverage Determination, can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. *See also* 42 C.F.R. § 405.1060. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that establishes criteria for coverage of selected types of medical items and services in the form of manuals and local coverage determinations ("LCDs").

Section 1869(f)(2) of the Act provides that Administrative Law Judges will give substantial deference to LCDs or CMS program guidance when applicable, and if they do not follow the policy they must explain why in their decision. *See also* 42 C.F.R. § 405.1062.

Applicable to the instant appeal is LCD L34823: Tumor Treatment Field Therapy (TTFT) (LCD L34823) (July 2016). For any item to be covered by Medicare, it must be eligible for a defined Medicare benefit category, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The LCD further states that CPT code E0766, tumor treatment field therapy will be denied as not medically reasonable and necessary. LCD L34823.

Historically, in making coverage determinations, CMS has interpreted the terms "reasonable and necessary" to mean that the item or service in question is safe and effective and not experimental. CMS has further determined that the relevant tests for applying these terms are whether the item or service has been proven safe and effective based on authoritative evidence, or alternatively, whether the item or service is generally accepted in the medical community as safe and effective for the condition for which it is used. 54 Fed. Reg. 4304 (Jan. 30, 1989); 60 Fed. Reg. 48417 (Sept. 19, 1995); *see also* 52 Fed. Reg. 15,560 (Apr. 29, 1987). Indeed, CMS has provided guidance in the

Medicare Program Integrity Manual (CMS Pub. 100-08) (*MPIM*) to assist contractors in developing LCDs to aid in creating relevant tests and guidance. The *MPIM* contemplates that, in making a determination as to whether an item or service is reasonable and necessary, contractors will analyze whether the item or service is safe and effective, and not experimental or investigational. *MPIM*, ch. 13, § 13.5.1. Contractors shall consider a service reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational; and
- Appropriate, including the duration and frequency that is considered appropriate for the service.

The *MPIM* further instructs contractors to base LCDs on the strongest evidence available at the time the determination is issued. In order of preference, this includes:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and ALJs and the Medicare Appeals Council are not bound by CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. 42 C.F.R. § 405.1062(a).
- General acceptance by the medical community (standards of practice), supported by sound medical evidence based on:
 - Scientific data or research studies published in peer-reviewed medical journals;
 - Consensus of expert medical opinion (i.e., recognized authorities in the field); or
 - Medical opinion derived from consultations with medical associations or other health care experts.

Id. at § 13.7.1. The Manual further explains:

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

ANALYSIS

The Beneficiary is challenging the denial of coverage for placement of electrical stimulation therapy she received for the dates of service of September 8, 2017, October 8, 2017, and November 8, 2017.

The QIC denied payment because the procedure was not medically reasonable and necessary. The evidence in this case supports a finding that Medicare should cover the procedure because it is medically reasonable and necessary for the Beneficiary.

On February 25, 2017, an MRI was performed on the Beneficiary, a 68 year-old female, revealing a lesion that was worrisome to the physicians for a Central Nervous System glioma, following episodes of involuntary movement. A progress note dated March 10, 2017, indicates that the Beneficiary underwent a right frontal craniotomy with partial resection of the right frontal mass on March 3, 2017. The surgical pathology report confirmed the diagnosis of GBM. The treatment plan included radiation, chemotherapy, Gamma knife surgery, and the Optune device. Approximately one month after the resection, specifically April 4, 2017, Gamma knife surgery was performed. The procedure note indicates that the Beneficiary thereafter resumed her fractionated radiation course.

According to Justin Kelly, Regional Vice President of Health Policy for the supplier of the Optune device, the Beneficiary was prescribed the Optune device in June 2017 following these numerous other treatments. Mr. Kelly further testified that the beneficiary's GBM progressed, representing clinical recurrence in August 2017.

At issue in this case is whether the documentation submitted established Medicare's coverage and payment requirements for payment under Part B of Title XVIII of the Social Security Act. The QIC and the Medicare Administrative Contractor found that the service was not covered by Medicare based on LCD L34823. The QIC correctly determined that LCD L34823 was in effect at the time the services were rendered and that the Optune device for the treatment of glioblastoma was non-covered by Medicare. The LCD plainly states that tumor treatment field therapy is not medically reasonable and necessary, without further explanation. The Beneficiary argues that "[n]o basis exists to deny Medicare coverage of a device that is shown in the peer-reviewed literature to be a safe and effective treatment for glioblastoma, a life-threatening condition. The Optune system was approved as safe and effective by the FDA. . . . The Medicare beneficiary has no reasonable medical alternatives." (Exh. 7, p. 5).

The applicable provisions in LCDs and Medicare manuals are entitled to substantial deference to the extent that they are consistent with the Act, regulations, and rulings. 42 C.F.R. § 405.1062. To the extent that an ALJ deviates from an LCD that deviation must be explained. Under the circumstances presented in this case, the ALJ finds substantial reason to deviate from this applicable LCD.

First, the medical literature submitted for review supports that the device is safe and effective for patients like the Beneficiary. The record contains numerous studies regarding the device, which the ALJ reviewed. One such study is the ET-14 study, which included patients who were newly diagnosed with glioblastoma upon initial presentation. While some patients experienced a recurrence during the study, they continued to be treated with the device per the study protocol. Therefore, the study on newly diagnosed glioblastoma reflected the effectiveness of the treatment on individuals who received the device when newly diagnosed, and those who continued using it during unfortunate recurrences. The results reflected statistically significant improvement in overall survival for patients diagnosed with glioblastoma generally.

The final analysis of the randomized phase 3 trial (695 patients) found that the addition of Optune for newly diagnosed cases, in addition to those who began the study as newly diagnosed patients but suffered recurrences, to standard chemotherapy treatment “resulted in statistically significant improvement in progression-free survival and overall survival” over patients that were treated with chemotherapy alone. The ET-14 study for the device at issue was deemed to have met its primary endpoints prior to its completion by the FDA and ended early, upon the recommendation of the trial's independent data monitoring committee, so as to provide the patients who were not receiving care with Optune the opportunity to receive such treatment.

Second, Optune is FDA-approved for recurrent and newly diagnosed GBM brain tumors. Glioblastoma is the most common form of primary brain cancer but is still very rare (~ 10,000 cases annually in the U.S.). The NIH designates GBM as a rare disease, with few treatment options. The Optune device has been certified at more than 800 cancer treatment centers, and has been prescribed by over 1200 physicians in 50 states, the District of Columbia, and Puerto Rico, for over 7200 patients for treatment of GBM. Virtually every major commercial payer in the United States covers the Optune device for individuals diagnosed with a glioblastoma. Policies in the record reflect coverage from payers such as Highmark, Aetna, Anthem, Humana, Kaiser, UnitedHealthcare, Cigna, Harvard Pilgrim, Geisinger, HealthPartners, and several Blue Cross plans. Additionally, the NCCN Clinical Practice Guidelines 2016 and 2017 for “Central Nervous System Cancers,” include Tumor Treatment Field Therapy (TTFT) treatment, like the Optune device for recurrent glioblastoma.

Third, in response to an LCD reconsideration request, the DMAC medical directors issued a letter, which indicates that they do not believe the non-coverage LCD L34823 addresses instances of newly diagnosed glioblastoma. Therefore, it is proper in this case to deviate from the applicable LCD because the record contains documentation regarding the safety and efficacy of the Optune device.

Having found reason to deviate from the applicable LCD, it must be determined whether the treatment was reasonable and medically necessary for the Beneficiary. A patient’s survival time with GBM at initial presentation is approximately 10 months, even with aggressive chemotherapy. Without additional effective treatment, the average overall survival is approximately 6 months from the time of recurrence. “Recurrent” GBM occurs when the tumor recurs or progresses after initial treatment. Recurrent GBM is an end-stage condition. When GBM recurs, patients are rarely eligible for re-operation. As a result, patients with recurrent GBM face severely limited treatment options.

Much like patients in the ET-14 study, the Beneficiary’s clinician prescribed the device when the Beneficiary was newly diagnosed with a glioblastoma. The Beneficiary did experience progression of her disease while using the Optune, such as other patients who participated in and remained in the ET-14 study per the protocol. The Beneficiary's clinical treatment circumstances mirror those of the ET-14 study, given her continued use of the Optune device that was originally prescribed when newly diagnosed.

Based on the above, the Optune device provided to the Beneficiary was medically reasonable and necessary. The Beneficiary met all of Medicare's coverage requirements for payment under Part B of Title XVIII of the Social Security Act. The Beneficiary submitted sufficient documentation to meet the documentation requirements of section 1833(e) of the Social Security Act. Therefore, the Beneficiary is entitled to reimbursement from Medicare for the electrical stimulation cancer treatment (E0766) for the dates of service of September 8, 2017, October 8, 2017, and November 8, 2017.

CONCLUSIONS OF LAW

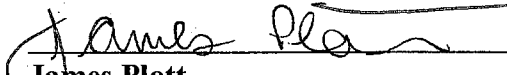
After careful consideration of all the evidence, Medicare Part B coverage is found for the electrical stimulation cancer treatment (E0766) for the dates of service of September 8, 2017, October 8, 2017, and November 8, 2017. The limitation of liability provisions of Section 1879 of the Act do not apply because this decision is favorable to the Beneficiary.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this Decision.

SO ORDERED.

Dated: OCT 17 2018


James Plott
U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, Missouri

Appeal of:	ALJ Appeal No.: 1-5223746965
Enrollee:	Medicare Part C
HICN:	Before: Aaron R. Raff U.S. Administrative Law Judge
MA Plan: Group Health Cooperative	

DECISION

After careful consideration of all the evidence and arguments presented in the hearing and record, this Administrative Law Judge (“ALJ”) enters a **FULLY FAVORABLE** decision for the Enrollee, Estate of [REDACTED] (“Enrollee”).

Procedural History

The Enrollee was prescribed and used Optune tumor treatment field therapy (“TTFT”), manufactured by NovoCure, Ltd. (“Provider”), for treatment of glioblastoma from October 28, 2015, to December 28, 2015. Group Health Cooperative, (the “Plan”) denied coverage initially and on redetermination. The decision was appealed and on October 4, 2016, MAXIMUS Federal Services, the Quality Improvement Organization (“QIO”), held that the Plan was not required to cover the TTFT. (Exh. 1, pp. 3-4).

On October 13, 2016, the Office of Medicare Hearings and Appeals (“OMHA”) received the Appellant’s timely request for an ALJ Hearing. 42 C.F.R. 422.600 and .602 (Part C) referring to 42 C.F.R. § 405.1014. On December 5, 2016, this ALJ held a hearing by telephone. Ms. [REDACTED] with the Provider, and [REDACTED], the Enrollee’s husband, appeared on behalf of the Enrollee’s Estate. On behalf of the Plan, Ms. D. Jackson, Ms. T. Nurse, and Dr. Sean Stitham, M.D. appeared. The parties were advised of their right to counsel and knowingly and intelligently waived the same. This ALJ carefully considered the hearing testimony, argument and record. Exhibits 1-7 were admitted into the record without objection, and the parties testified under oath.

Issues

1. Whether the contract coverage provisions have been met warranting payment?

Findings of Fact

After careful consideration of the entire record (Exhibit List attached and incorporated herein), a preponderance of the evidence establishes the following facts:

1. All jurisdictional requirements of this case have been met.
2. The QIO held that Medicare rules, in particular Local Coverage Determination L34823, state that TTFT will be denied as not reasonable and necessary. (Exh. 1).
3. The Enrollee was a 65-year-old female on the dates of service. (Exh. 2, pp. 12-14). On March 9, 2015, the Enrollee presented to urgent care with weakness and headaches. (Exh. 2, pp. 15-20). At urgent care, the Enrollee underwent a CT scan and MRI imaging, which found a contrast-enhancing mass in her right frontal lobe. *Id.*
4. On March 11, 2015, the Enrollee underwent a right frontal craniotomy and tumor resection, from which the Enrollee made a complete recovery. *Id.* Resultant pathology was consistent with glioblastoma. *Id.*
5. Glioblastoma is an aggressive, malignant, primary brain tumor. *Id.* Prognosis for glioblastoma is poor and has a median survival time of approximately 14 months, despite multiple available treatments including craniotomy with surgical resection, chemo-radiotherapy, antiangiogenic therapy, and symptomatic management. *Id.*
6. The Enrollee began temozolomide-based chemoradiation on April 9, 2015. *Id.* In July 2015, the enrollee commenced postradiation Temodar. *Id.* However, later in July, she was found to have disease progression. *Id.* After a second round of Temodar followed by continued disease progression, the Enrollee was started on Avasin in combination with lomustine. *Id.*
7. Physician notes from July 22, 2015, stated that the Beneficiary's residual tumor appeared to be more conspicuous than seen in imaging following resection and that a new lesion was also noted. (Exh. 2, pp. 31-33).
8. In sum, prior to the TTFT at issue, the Enrollee tried a mixture of radiation, chemotherapy and surgery treatments without sufficient success. The glioblastoma has reoccurred. (Exh. 3 and Hearing testimony.)
9. On July 22, 2015, September 29, 2015, and March 23, 2016, the Enrollee was prescribed Optune with each prescription valid for a six month period. (Exh. 2, p. 12-14).

10. Optune uses low-intensity electric fields to help slow or stop glioblastoma cancer cells from dividing.¹ Four adhesive patches, or transducer arrays, are applied to the scalp and connected to the device and a battery to deliver the therapy. *Id.*
11. Optune, previously called NovoTTF-100A System, received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011.²
12. On October 5, 2015, the Provider received premarket approval from the FDA for use of Optune in patients newly diagnosed with glioblastoma.³
13. The Enrollee became a member of the MA Plan on October 1, 2015, upon turning 65. (Exh. 1, p. 8). Prior to joining the MA Plan, the Enrollee was a member of the Group Health Cooperative commercial plan. (Hearing testimony).
14. In physician notes from November 17, 2015, after initiation of Optune coupled with Avastin and lomustine, the Enrollee was noted to have no evidence of disease progression, by either contrast enhancement or FLAIR signal abnormalities. (Exh. 2, pp. 27-28).
15. Reports from an MRI performed on March 17, 2016, showed stable clinical and radiographic evaluation and no change in the volume of the Enrollee's tumor. (Exh. 2, p. 21).
16. On May 3, 2016, Group Health commercial plans began coverage of the Optune device to treat primary supratentorial glioblastoma. (Exh. 1, p. 9). On July 26, 2013, CMS also provided an informal benefit category determination to NovoCure regarding the NovoTTF-100A System. (Exh. 3, p. 53). This letter indicated that the NovoTTF-100A System would fall within the definition of durable medical equipment. *Id.*
17. In an article published in July 2015 in Current Treatment Options in Oncology, results of a phase III clinical trial for recurrent glioblastoma were discussed, as well as interim results in a study involving patients newly diagnosed with glioblastoma. *See* 16 Curr. Treat. Options in Oncol. 40 (2015); (Exh. 3, pp. 31-41). This article reported that TTFT was "shown to have equivalent efficacy when compared to the best physician's choice chemotherapy in a registration phase III clinical trial for recurrent glioblastoma." *Id.* The results of this clinical trial then led to FDA approval for the device. *Id.* Interim results of a later clinical trial for newly diagnosed patients showed significant improvement in outcomes of the patients, leading to crossover of trial subjects from the control group to the experimental group. *Id.*
18. On December 15, 2015, the Journal of the American Medical Association ("JAMA") published an article analyzing the results of a phase III clinical trial related to TTFT.⁴

¹ See <https://www.optune.com/therapy/how-therapy-works>.

² http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100034a.pdf.

³ http://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034S013a.pdf.

The analysis of the clinical trial showed that adding TTFT to maintenance temozolomide in a population with new onset glioblastoma “significantly prolonged progression-free and overall survival.” *Id.* After conclusion of the study, patients in the control group with ongoing maintenance therapy were offered TTFT therapy. *Id.* Thirty-five of those patients chose to receive TTFT therapy. *Id.*

19. The National Comprehensive Cancer Network (“NCCN”) included alternating electric field therapy for glioblastoma in its NCCN Clinical Practice Guidelines in oncology Central Nervous System Cancers guidelines version 1.2015. (Exh. 3, pp. 26-30).
20. At hearing, the Provider explained the Enrollee’s medical history and progression of the glioblastoma. (Hearing testimony). After multiple rounds of treatment, disease progression was found. *Id.* The Enrollee began using the Optune device on September 28, 2015, after which the disease was shown to be stable at the latest on November 12, 2015. *Id.* The Optune device received FDA approval in April 2011 for use with recurrent glioblastoma. *Id.* The device exhibits minimal toxicity and provides patients with a better quality of life than other treatments. *Id.* Further, the NCCN guidelines were updated in 2015 to include alternating electric field therapy for treatment of glioblastoma. *Id.* The Provider also explained that the Enrollee had undergone surgery, radiation, and chemotherapy and her disease continued to progress. *Id.* As of July 2015, the Enrollee did not have significant alternative treatments to slow the progression of her disease. *Id.* Finally, the Provider argued that the Local Coverage Determination relevant to this case did not examine or take into consideration literature more recent than 2013. *Id.*
21. The Enrollee’s husband reported that the Enrollee had undergone surgery, chemotherapy, and radiation and that the MA Plan offered no other treatment options. (Hearing testimony). In July 2015, the Enrollee was able to see Dr. REDACTED who prescribed the Optune device. *Id.* After treatment began, the disease progress halted for many months prolonging the lifespan of the Enrollee, explained the Enrollee’s husband. *Id.* The Enrollee’s husband stated that the Enrollee used the device continuously and as much as possible until the point at which the disease began to progress again. *Id.* The Optune treatment gave the Enrollee months of life without advancement of the disease. *Id.*
22. With regard to Dr. REDACTED the Enrollee’s neuro-oncologist, the Enrollee’s husband reported that Dr. REDACTED is part of the Seattle Cancer Care Alliance. *Id.* While the Enrollee was a member of the MA Plan’s commercial plan, the Enrollee was referred to Dr. REDACTED by the commercial plan. *Id.* Dr. REDACTED was the only physician in the area able to continue treatment with the Enrollee, reported the Enrollee’s husband. *Id.*
23. The Plan argued that the relevant Local Coverage Determination stated that Tumor Treatment Field Therapy was not covered by Medicare as not medically reasonable and

⁴ Stupp, Roger, M.D. et al., *Maintenance Therapy With Tumor-Treating Field Plus Temozolomide vs Temozolomide Alone for Glioblastoma A Randomized Clinical Trial*, 314 JAMA 2535 (2015); (Exh. 2, pp. 1-11).

necessary treatment. (Hearing testimony). Although this therapy could be approved under certain circumstances on the commercial side, the MA Plan is bound to follow Local Coverage Determinations. *Id.* The MA Plan also argued that prior authorization for the physician was not given and that the services were not ordered by a physician who was part of the MA Plan. *Id.*

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

A party that is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services, provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. 42 C.F.R. 422.600 and .602 (Part C) referring to 42 C.F.R. § 405.1014; Social Security Act (“the Act”) section 1869(b)(1)(A). The Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, unless later reviewed by the Medicare Appeals Council. *Id.*

To be considered timely, the request for hearing must be received by OMHA within sixty days after the Appellant receives the QIC’s reconsideration decision. The Appellant is presumed to have received the QIC’s reconsideration five days after the date noted on the first page of the reconsideration, unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3).

B. Scope of Review

The ALJ considers all issues not decided entirely in the Appellant’s favor at any prior level of review. 42 C.F.R. § 405.1032. This ALJ may give notice to the parties if any other issue will be addressed at the hearing. *Id.* This ALJ may also issue a decision on the record on his or her own initiative if the evidence in the hearing record supports a fully favorable finding. 42 C.F.R. §§ 405.1000(g), 405.1038(a).

C. Standard of Review

The ALJ reviews and evaluates the evidence without regard to the findings made by the lower levels on the claim (*de novo* review). 42 C.F.R. § 405.1000(d). The Appellant bears the burden of proving each element of the Medicare claim. Act §§ 1814(a)(1), 1815(b), 1833(e); 42 C.F.R. §§ 424.5(a)(6), 405.1018, 405.1028, 405.1030.

II. Principles of Law

A. Statutes & Regulations

The Medicare Advantage (“MA”) program (Part C) provides that a MA organization offering a MA plan must provide enrollees, at a minimum, with all basic Medicare-covered services by furnishing the benefits directly or through arrangements, or by paying for the benefits. Basic benefits are benefits defined as “all Medicare covered services, except hospice services.” Mandatory supplemental benefits are defined as “services not covered by Medicare that an MA enrollee must purchase as part of an MA plan that are paid for in full, directly by (or on behalf of) Medicare enrollees, in the form of premiums or cost sharing. Optional supplemental benefits are defined as “health services not covered by Medicare that are purchased at the option of the MA enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost sharing. These services may be grouped or offered individually.” Act §1852(a); 42 CFR § 422.100.

An MA organization’s health plan must provide coverage for all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B). Further, MA organizations must comply with national coverage determinations as promulgated by the Centers for Medicare and Medicaid Services, general coverage guidelines included in original Medicare manuals and instructions, and written coverage decisions of local Medicare contractors with jurisdiction. 42 CFR § 422.101.

Notwithstanding any other provision of Title XVIII, “no payment may be made under part A or part B for any expenses incurred for items or services-which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” Act § 1862(a)(1). Custodial care expenses are also excluded from Medicare Coverage. Act § 1862(a)(9); 42 C.F.R. § 411.15(g), (k).

B. Policy and Guidance

ALJ’s must give the manuals and rulings substantial deference. 42 C.F.R. § 405.1062(a). Unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than a National Coverage Determination (“NCD”), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. Act § 1871(a)(2); 42 C.F.R. § 405.1060. However, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local coverage determinations (“LCDs”). The applicable provisions in the LCDs and Medicare manuals are entitled to substantial deference to the extent they are consistent with the Act, regulations, and rulings; deviation from them must be explained. 42 C.F.R. § 405.1062. All relevant LCDs and Medicare manuals are hereby given substantial deference. 42 C.F.R. § 406.1060.

MA organizations must comply with national coverage determinations as promulgated by the Centers for Medicare and Medicaid Services, in addition to general coverage guidelines included

in original Medicare manuals and instructions, and written coverage decisions of local Medicare contractors with jurisdiction. 42 C.F.R. § 422.101.

A Noridian Administrative Services Local Coverage Determination, LCD L34823, Tumor Treatment Field Therapy is relevant for this case. This LCD provides that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. Noridian Admin. Serv., Local Coverage Determination L34823: Tumor Treatment Field Therapy (LCD L34823) (Oct. 2015). The related Policy Article states that tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit and must meet the reasonable and necessary requirements set out in the related LCD to be eligible for reimbursement. Noridian Admin. Serv., Local Coverage Article for Tumor Treatment Field Therapy Article A52711 (Article A52711) (Oct. 2015).

The Medicare Program Integrity Manual (CMS Pub. 100-08) (MPIM), ch. 13 § 13.5.1, and the Medicare Benefit Policy Manual (CMS Pub. 100-02) (MBPM), ch. 15 § 110, provide guidance for determining whether a device is reasonable and necessary. These manuals suggest that a device is not reasonable and necessary if it is:

- Not “safe” and “effective” – that is, if the device has not been “proven safe and effective based on authoritative evidence” or is not “generally accepted in the medical community as safe and effective for the condition for which it is used.”
- “Experimental” – that is, “investigational”;
- Not “[a]ppropriate” for the individual beneficiary’s needs; or
- “[S]ubstantially more costly than a medically appropriate and realistically feasible alternative pattern of care.”

See also Almy v. Sebelius, 679 F.3d 297, 299 (4th Cir. 2012).

The claimant has the burden to show that the device is reasonable and necessary. *Almy*, 679 F.3d at 305.

Medicare also instructs contractors as to the type of evidence to be used in making these technical determinations. Such decisions should be based on either “published authoritative evidence” such as “definitive randomized clinical trials” or “general acceptance by the medical community,” with the caveat that “[a]cceptance by individual health care providers” and “limited case studies distributed by sponsors with a financial interest in the outcome[] are not sufficient evidence of general acceptance by the medical community.” MPIM § 13.7.1; *see also Almy*, 679 F.3d at 300.

C. Medicare Advantage (“MA”) Plan

Group Health Cooperative’s Evidence of Coverage details the services covered by the MA Plan. (Exh. 5). The Plan covers all services covered by Original Medicare and must follow Original Medicare’s coverage rules. (Exh. 5, p. 44). Medically necessary is defined in the MA Plan Evidence of Coverage as “services, supplies, or drugs [which] are needed for the prevention, diagnosis, or treatment of your medical condition and meet accepted standards of medical practice.” *Id.*

Analysis

This Administrative Law Judge conducted a *de novo* review of the evidence to determine whether the Appellant established the requirements for Medicare coverage. Appellant's request for an ALJ hearing was timely and satisfied jurisdictional requirements. In this case, this ALJ finds and concludes that the tumor treatment field therapy for treatment of this Enrollee's glioblastoma for the dates of service was medically reasonable and necessary.

Medicare Advantage plans must pay for a medical service if original Medicare would cover it. 42 C.F.R. § 422.101. The Plan may also offer additional benefits to those covered by original Medicare if it so chooses. 42 C.F.R. § 422.102. The Plan in this case covers all services provided by original Medicare. (Exh. 4, p. 44).

First, this ALJ notes that there is no National Coverage Determination specific to tumor treatment field therapy. This ALJ, therefore, looks to the relevant LCD for guidance. ALJs are not bound by LCDs and will give substantial deference to the policies if they are applicable to a particular case. 42 C.F.R. § 405.1062. If an ALJ declines to follow an LCD in a particular case, the ALJ must explain the reasons why the policy was not followed. *Id.*

In this case, this ALJ declines to follow LCD L34823⁵ for multiple reasons as further discussed. In general, this ALJ finds that the therapy has been shown to be safe and effective for use in patients with recurrent glioblastoma (after chemotherapy, radiation and/or surgery has been tried without sufficient success, all as here with this Enrollee) and it is medically reasonable and necessary to treat the Enrollee's condition.⁶

The relevant LCD states that tumor treatment field therapy will be denied as not reasonable and necessary. However, this ALJ notes that the Information and Basis of Decision section of the applicable version LCD showed that the most recent literature reviewed for purposes of the LCD's formation was published in 2013. If additional or more recent literature was reviewed, it is not listed in the LCD. LCD L34823.

In any event, the advancement of medicine and science can sometimes outpace the current or relevant version of an LCD. Subsequently reported data from the FDA, phase III clinical trials and NCCN guidelines is available to this ALJ for review and analysis, and shows the LCD may be behind the medical literature curve as applied to this patient. The ALJ now reasons through the evidence in the record and the parties' contentions in more detail below.

⁵ Using the LCD version in effect at the time of service. There is a later 2016 version as well.

⁶ The MA Plan also mentioned at hearing that the Enrollee's physician was not a network physician with the MA Plan (but may be in the group on the commercial side). The record does not show that this issue was raised at prior levels of review for these claims. (Exh. 1). Correspondence in the record showed that representatives from the QIO and MA Plan discussed the network status of the referring physician, but no evidence showed that the Enrollee was privy to that correspondence. Further, the record did not show that the QIO or the MA Plan based their respective written coverage denials on the issue of the physician's network status. The ALJ may only consider a new issue at the hearing if he or she notifies all parties about the issue before the start of hearing. 42 C.F.R. 405.1032(b). On this record, the possible in-network topic or sub-issue was never properly raised below. The Enrollee did not have an opportunity to prepare and present evidence relevant to this argument at the ALJ level, and the ALJ declines to expand the issues.

First, this ALJ finds that the Optune device received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011. On October 5, 2015, the FDA gave premarket approval for use of Optune in patients with newly diagnosed glioblastoma. The FDA website explains that premarket approval ("PMA") entails the following:

PMA is the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).⁷

While FDA premarket approval does not establish that the device is medically reasonable and necessary pursuant to Medicare requirements, it does ensure that the FDA has closely examined the device and its application. In this case, the FDA determined that sufficient scientific evidence existed to provide the FDA with assurance that the device was safe and effective for its intended use both in patients with recurrent and newly diagnosed glioblastoma. From this perspective, the use of the device meets Medicare guidance requiring that a device be proven safe and effective based on authoritative evidence.

The FDA approval, along with the other evidence below, also helps shows that the device is safe, and not experimental or investigational Medicare does not pay for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. Act § 1862(a)(1). To be reasonable and necessary, the procedure must be safe and effective and not experimental.

Second, this ALJ has reviewed clinical studies in the record related to the use of the Optune device. Results from a phase III clinical trial utilizing TTFT in patients with recurrent glioblastoma was shown to have equivalent efficacy when compared to the best physician's choice for chemotherapy. (Exh. 3, pp 31-41 et seq.). With respect to patients newly diagnosed with glioblastoma, results of a phase III study released in a December 15, 2015, JAMA article showed that adding TTFT to maintenance temozolomide significantly prolonged progression-free and overall survival. *Id.* Significantly, patients in the control group in the JAMA-reported study crossed over to the combined therapy group for TTFT treatment due to the improvement in outcomes seen. *Id.* The results from these phase III trials also led to FDA approval for the Optune device. *Id.* Again, these trials showed that the Optune device was safe, non-investigational and effective. In addition, these trials showed that the Optune device was appropriate for this individual Enrollee's needs, specifically the treatment of recurrent glioblastoma.

Third, the use of TTFT is generally accepted by the medical community. In the 2015 version of the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology Central Nervous System Cancers guidelines, alternating electric field therapy is a treatment option suggested for glioblastoma. (Exh. 3, pp. 26-30). This suggestion was found in a treatment

⁷<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm>

guideline from a national cancer organization, not evidence based on an individual physician treating a single patient in a clinical setting. As such, this ALJ finds that TTFT treatment is generally accepted in the medical community as safe and effective for the treatment of recurrent glioblastoma.

Overall, a review of the literature available showed that the Optune device received FDA premarket approval, showing that it was safe and effective and not investigational/experimental. The use of the Optune device in a population with recurrent glioblastoma was proven effective and appropriate through a phase III clinical trial; and the use of the Optune device appears in national cancer treatment guidelines for treatment of glioblastoma, showing general acceptance by the medical community. A number of commercial health plans also now cover TTFT.

The final aspect is the medical record of this specific Enrollee, who has since passed away after a difficult battle with glioblastoma. A review of the medical records and hearing demonstrated that the Enrollee had already undergone surgical resection of the tumor, chemoradiation, and postradiation chemotherapy. When she began treatment with the Optune (TTFT) device, the Enrollee had exhausted other treatment options and her disease continued to recur and progress. This Enrollee had no feasible alternative pattern of care available to her to halt the progression of her disease. After beginning treatment, the Enrollee's disease progression stopped, which prolonged or helped prolong the lifespan of the Enrollee by several precious months. For the Enrollee, the preponderance of the evidence is that the TTFT therapy helped in these trying circumstances.

For the reasons stated above, this ALJ finds that Optune (TTFT) has been shown to be safe and effective and was medically reasonable and necessary for the treatment of this Enrollee's condition for the dates of service in question.

Conclusions of Law

This decision is **FULLY FAVORABLE** for the Appellant/Enrollee. This Administrative Law Judge decides that the Optune device using tumor treatment field therapy (TTFT) was medically reasonable and necessary for the treatment of the Enrollee's glioblastoma for the dates of service from October 28, 2015, to December 28, 2015. Therefore, the Plan shall cover the related care for the Enrollee.


Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

DEC 22 2016

Dated: _____



Aaron R. Raff
U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, Missouri

Appeal of:	ALJ Appeal No.: 1-6210417199
Enrollee:	Medicare Part C
HICN: *****9958A	Before: Aaron R. Raff U.S. Administrative Law Judge
MA Plan: Humana	

DECISION

After careful consideration of all the evidence and arguments presented in the hearing and record, this Administrative Law Judge ("ALJ") enters a **FULLY FAVORABLE** decision for the Enrollee, "Enrollee").

Procedural History

The Enrollee requested pre-approval for Tumor Treatment Field Therapy (TTFT) (E0766). Humana, (the "Plan") denied coverage initially and on redetermination. The decision was appealed and on April 3, 2017, MAXIMUS Federal Services held that the Plan was not required to cover the TTFT. (Exh. 1, pp. 3-4).

On May 4, 2017, the Office of Medicare Hearings and Appeals ("OMHA") received the Appellant's timely request for an ALJ Hearing. 42 C.F.R. 422.600 and .602 (Part C) referring to 42 C.F.R. § 405.1014. On July 27, 2017, this ALJ held a hearing by telephone. The Enrollee appeared by his representative Sean McGartland of Novocare. The Plan appeared by Cynthia McCloud and Dr. Martha Willoughey, M.D. The parties were advised of their right to counsel and knowingly and intelligently waived the same. This ALJ carefully considered the hearing testimony, argument and record. All exhibits were admitted into the record without objection, and the parties testified under oath.

Issues

The issues before the Administrative Law Judge include all of the issues brought out in the initial determination, coverage determination, or organization determination; redetermination; or reconsideration that were not decided entirely in a party's favor, for the claims or other appealed matters specified in the request for hearing.

Findings of Fact

After careful consideration of the entire record (Exhibit List attached and incorporated herein), a preponderance of the evidence establishes the following facts:

1. The Medicare Part C Independent Review Entity ("IRE") determined that Humana did not have to pre-approve the requested device or treatment. (Exh. 1, pp. 3-4). In reaching this decision the IRE relied on local coverage determination L34823 which stated that tumor treatment field therapy and related devices will be denied as not reasonable and necessary. *Id.*
2. The Enrollee became active with Humana on January 1, 2013. (Exh. 3, p. 7).
3. The Enrollee is a 70 year old male. (Exh. 2, p. 4; Hearing testimony). On March 9, 2016, the Enrollee presented to his physician with complaints of headache, disorientation, and gait imbalances. *Id.* An MRI revealed a 4.5 x 3.3 x 3.6 cm T1 and T heterogeneous medical right temporal lobe mass lesion with hemorrhage. *Id.*
4. On March 11, 2016, the Enrollee underwent a right frontal craniotomy and tumor resection. (Exh. 2, pp. 4, 15-17, 21). Resultant pathology was consistent with glioblastoma. *Id.*

5. Glioblastoma is an aggressive, malignant, primary brain tumor. (Exh. 1, p. 14). Prognosis for glioblastoma is poor and has a median survival time of approximately 14 months, despite multiple available treatments including craniotomy with surgical resection, chemotherapy, radiotherapy antiangiogenic, and symptomatic management.
6. The Enrollee completed Temodar on April 7, 2016. (Exh. 2, p. 4).
7. Physician notes dated February 3, 2017, indicated that the Beneficiary's last MRI showed recurrence and swelling. (Exh. 2, pp. 4-8, 26). In sum, prior to the TTFT at issue, the Enrollee tried a mixture of radiation, chemotherapy and surgery treatments without sufficient success. The glioblastoma had reoccurred. (Exh. 2).
8. On February 3, 2017, the Enrollee was prescribed Optune for a six month period. (Exh. 2, p. 2; Hearing testimony).

9. Optune uses low-intensity electric fields to help slow or stop glioblastoma cancer cells from dividing. (Exh. 3, p. 271). Four adhesive patches, or transducer arrays, are applied to the scalp and connected to the device and a battery to deliver the therapy. *Id.*
10. Optune, previously called NovoTTF-100A System, received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011.¹ (Exh. 1, p. 11; Exh. 2, pp. 114-118; Hearing testimony). The device was indicated for treatment of adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme, following histologically-or radiologically confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. *Id.*
11. In 2015, the National Comprehensive Cancer Network guidelines were updated to include TTFields treatment for recurrent glioblastoma. (Exh. 1, p. 13; Hearing testimony).
12. In an article published in July 2015 in Current Treatment Options in Oncology, results of a phase III clinical trial for recurrent glioblastoma were discussed, as well as interim results in a study involving patients newly diagnosed with glioblastoma. *See* 16 Curr. Treat. Options in Oncol. 40 (2015); (Exh. 2, pp. 101-110). This article reported that TTFT was “shown to have equivalent efficacy when compared to the best physician’s choice chemotherapy in a registration phase III clinical trial for recurrent glioblastoma.” *Id.* The results of this clinical trial then led to FDA approval for the device. *Id.* Interim results of a later clinical trial for newly diagnosed patients showed significant improvement in outcomes of the patients, leading to crossover of trial subjects from the control group to the experimental group. *Id.*
13. On December 15, 2015, the Journal of the American Medical Association (“JAMA”) published an article analyzing the results of a phase III clinical trial related to TTFT.² (Exh. 3, pp. 369-379). The analysis of the clinical trial showed that adding TTFT to maintenance temozolomide in a population with new onset glioblastoma “significantly prolonged progression-free and overall survival.” *Id.* After conclusion of the study, patients in the control group with ongoing maintenance therapy were offered TTFT therapy. *Id.* Thirty-five of those patients chose to receive TTFT therapy. *Id.*
14. The National Comprehensive Cancer Network (“NCCN”) included alternating electric field therapy for glioblastoma in its NCCN Clinical Practice Guidelines in oncology Central Nervous System Cancers guidelines version 1.2015. (Exh. 3, pp. 365-368).
15. At hearing, the Appellant explained the Enrollee’s medical history and progression of the glioblastoma. (Hearing testimony). After multiple rounds of treatment, disease progression was found. *Id.* The Enrollee began using the Optune device on February 27, 2017. *Id.* The Optune device received FDA approval in April 2011 for use with recurrent glioblastoma and exhibits minimal toxicity and provides patients with a better

¹ http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100034a.pdf.

² Stupp, Roger, M.D. et al., *Maintenance Therapy With Tumor-Treating Field Plus Temozolomide vs Temozolomide Alone for Glioblastoma A Randomized Clinical Trial*, 314 JAMA 2535 (2015); (Exh. 3, pp. 369-379).

quality of life than other treatments. *Id.* Further, the NCCN guidelines were updated in 2015 to include alternating electric field therapy for treatment of glioblastoma. *Id.* The Appellant further argued that if the Enrollee had a commercial plan he may have received coverage. *Id.*

16. The listed support for the LCD is based on literature from 2013 and earlier. (Hearing testimony).
17. The Plan argued that the relevant Local Coverage Determination stated that Tumor Treatment Field Therapy was not covered by Medicare as not medically reasonable and necessary treatment. (Hearing testimony).

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

A party that is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services, provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. 42 C.F.R. 422.600 and .602 (Part C) referring to 42 C.F.R. § 405.1014; Social Security Act (“the Act”) section 1869(b)(1)(A). The Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, unless later reviewed by the Medicare Appeals Council. *Id.*

To be considered timely, the request for hearing must be received by OMHA within sixty days after the Appellant receives the QIC’s reconsideration decision. The Appellant is presumed to have received the QIC’s reconsideration five days after the date noted on the first page of the reconsideration, unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3).

B. Scope of Review

The ALJ considers all issues not decided entirely in the Appellant’s favor at any prior level of review. 42 C.F.R. § 405.1032. This ALJ may give notice to the parties if any other issue will be addressed at the hearing. *Id.* This ALJ may also issue a decision on the record on his or her own initiative if the evidence in the hearing record supports a fully favorable finding. 42 C.F.R. §§ 405.1000(g), 405.1038(a).

C. Standard of Review

The ALJ reviews and evaluates the evidence without regard to the findings made by the lower levels on the claim (*de novo* review). 42 C.F.R. § 405.1000(d). The Appellant bears the burden of proving each element of the Medicare claim. Act §§ 1814(a)(1), 1815(b), 1833(e); 42 C.F.R. §§ 424.5(a)(6), 405.1018, 405.1028, 405.1030.

II. Principles of Law

A. Statutes & Regulations

The Medicare Advantage (“MA”) program (Part C) provides that a MA organization offering a MA plan must provide enrollees, at a minimum, with all basic Medicare-covered services by furnishing the benefits directly or through arrangements, or by paying for the benefits. Basic benefits are benefits defined as “all Medicare covered services, except hospice services.” Mandatory supplemental benefits are defined as “services not covered by Medicare that an MA enrollee must purchase as part of an MA plan that are paid for in full, directly by (or on behalf of) Medicare enrollees, in the form of premiums or cost sharing. Optional supplemental benefits are defined as “health services not covered by Medicare that are purchased at the option of the MA enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost sharing. These services may be grouped or offered individually.” Act §1852(a); 42 CFR § 422.100.

An MA organization’s health plan must provide coverage for all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B). Further, MA organizations must comply with national coverage determinations as promulgated by the Centers for Medicare and Medicaid Services, general coverage guidelines included in original Medicare manuals and instructions, and written coverage decisions of local Medicare contractors with jurisdiction. 42 CFR § 422.101.

Notwithstanding any other provision of Title XVIII, “no payment may be made under part A or part B for any expenses incurred for items or services-which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” Act § 1862(a)(1). Custodial care expenses are also excluded from Medicare Coverage. Act § 1862(a)(9); 42 C.F.R. § 411.15(g), (k).

B. Policy and Guidance

ALJ’s must give the manuals and rulings substantial deference. 42 C.F.R. § 405.1062(a). Unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than a National Coverage Determination (“NCD”), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. Act § 1871(a)(2); 42 C.F.R. § 405.1060. However, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local coverage determinations (“LCDs”). The applicable provisions in the LCDs and Medicare manuals are entitled to substantial deference to the extent they are consistent with the Act, regulations, and rulings; deviation from them must be explained. 42 C.F.R. § 405.1062. All relevant LCDs and Medicare manuals are hereby given substantial deference. 42 C.F.R. § 406.1060.

MA organizations must comply with national coverage determinations as promulgated by the Centers for Medicare and Medicaid Services, in addition to general coverage guidelines included

in original Medicare manuals and instructions, and written coverage decisions of local Medicare contractors with jurisdiction. 42 C.F.R. § 422.101.

A CGS Administrators LLC, Local Coverage Determination, LCD L34823, Tumor Treatment Field Therapy is relevant for this case. This LCD provides that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. CGS Administrators, LLC, Local Coverage Determination L34823: Tumor Treatment Field Therapy (LCD L34823) (Jan. 2017). The related Policy Article states that tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit and must meet the reasonable and necessary requirements set out in the related LCD to be eligible for reimbursement. CGS Administrators, LLC, Local Coverage Article for Tumor Treatment Field Therapy Article A52711 (Article A52711) (Jan. 2017).

The Medicare Program Integrity Manual (CMS Pub. 100-08) (MPIM), ch. 13 § 13.5.1, and the Medicare Benefit Policy Manual (CMS Pub. 100-02) (MBPM), ch. 15 § 110, provide guidance for determining whether a device is reasonable and necessary. These manuals suggest that a device is not reasonable and necessary if it is:

- Not “safe” and “effective” – that is, if the device has not been “proven safe and effective based on authoritative evidence” or is not “generally accepted in the medical community as safe and effective for the condition for which it is used.”
- “Experimental” – that is, “investigational”;
- Not “[a]ppropriate” for the individual beneficiary’s needs; or
- “[S]ubstantially more costly than a medically appropriate and realistically feasible alternative pattern of care.”

See also *Almy v. Sebelius*, 679 F.3d 297, 299 (4th Cir. 2012).

The claimant has the burden to show that the device is reasonable and necessary. *Almy*, 679 F.3d at 305.

Medicare also instructs contractors as to the type of evidence to be used in making these technical determinations. Such decisions should be based on either “published authoritative evidence” such as “definitive randomized clinical trials” or “general acceptance by the medical community,” with the caveat that “[a]cceptance by individual health care providers” and “limited case studies distributed by sponsors with a financial interest in the outcome[] are not sufficient evidence of general acceptance by the medical community.” MPIM § 13.7.1; see also *Almy*, 679 F.3d at 300.

C. Medicare Advantage (“MA”) Plan

Humana’s Evidence of Coverage details the services covered by the MA Plan. (Exh. 3). The Plan covers all services covered by Original Medicare and must follow Original Medicare’s coverage rules. (Exh. 3, p. 60). Medically necessary is defined in the MA Plan Evidence of Coverage as “services, supplies, or drugs [which] are needed for the prevention, diagnosis, or treatment of your medical condition and meet accepted standards of medical practice.” *Id.*

Analysis

This Administrative Law Judge conducted a *de novo* review of the evidence to determine whether the Appellant established the requirements for Medicare coverage. Appellant's request for an ALJ hearing was timely and satisfied jurisdictional requirements. In this case, this ALJ finds and concludes that the tumor treatment field therapy for treatment of this Enrollee's glioblastoma for the dates of service was medically reasonable and necessary.

Medicare Advantage plans must pay for a medical service if original Medicare would cover it. 42 C.F.R. § 422.101. The Plan may also offer additional benefits to those covered by original Medicare if it so chooses. 42 C.F.R. § 422.102. The Plan in this case covers all services provided by original Medicare. (Exh. 4, p. 44).

First, this ALJ notes that there is no National Coverage Determination specific to tumor treatment field therapy. This ALJ, therefore, looks to the relevant LCD for guidance. ALJs are not bound by LCDs and will give substantial deference to the policies if they are applicable to a particular case. 42 C.F.R. § 405.1062. If an ALJ declines to follow an LCD in a particular case, the ALJ must explain the reasons why the policy was not followed. *Id.*

In this case, this ALJ declines to follow LCD L34823 for multiple reasons as further discussed. In general, this ALJ finds that the therapy has been shown to be safe and effective for use in patients with recurrent glioblastoma (after chemotherapy, radiation and/or surgery has been tried without sufficient success, all as here with this Enrollee) and it is medically reasonable and necessary to treat the Enrollee's condition.

The relevant LCD states that tumor treatment field therapy will be denied as not reasonable and necessary. However, this ALJ notes that the Information and Basis of Decision section of the applicable version LCD showed that the most recent literature reviewed for purposes of the LCD's formation was published in 2013. If additional or more recent literature was reviewed, it is not listed in the LCD. LCD L34823.

In any event, the advancement of medicine and science can sometimes outpace the current or relevant version of an LCD. Subsequently reported data from the FDA, phase III clinical trials and NCCN guidelines is available to this ALJ for review and analysis, and shows the LCD may be behind the medical literature curve as applied to this patient. The ALJ now reasons through the evidence in the record and the parties' contentions in more detail below.

First, this ALJ finds that the Optune device received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011. On October 5, 2015, the FDA gave premarket approval for use of Optune in patients with newly diagnosed glioblastoma. The FDA website explains that premarket approval ("PMA") entails the following:

PMA is the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the

PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).³

While FDA premarket approval does not establish that the device is medically reasonable and necessary pursuant to Medicare requirements, it does ensure that the FDA has closely examined the device and its application. In this case, the FDA determined that sufficient scientific evidence existed to provide the FDA with assurance that the device was safe and effective for its intended use both in patients with recurrent and newly diagnosed glioblastoma. From this perspective, the use of the device meets Medicare guidance requiring that a device be proven safe and effective based on authoritative evidence.

The FDA approval, along with the other evidence below, also helps shows that the device is safe, and not experimental or investigational Medicare does not pay for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. Act § 1862(a)(1). To be reasonable and necessary, the procedure must be safe and effective and not experimental.

Second, this ALJ has reviewed clinical studies in the record related to the use of the Optune device. Results from a phase III clinical trial utilizing TTFT in patients with recurrent glioblastoma was shown to have equivalent efficacy when compared to the best physician's choice for chemotherapy. (Exh. 2, pp. 101-110). With respect to patients newly diagnosed with glioblastoma, results of a phase III study released in a December 15, 2015, JAMA article showed that adding TTFT to maintenance temozolomide significantly prolonged progression-free and overall survival. (Exh. 3, pp. 369-379). Significantly, patients in the control group in the JAMA-reported study crossed over to the combined therapy group for TTFT treatment due to the improvement in outcomes seen. *Id.* The results from these phase III trials also led to FDA approval for the Optune device. *Id.* Again, these trials showed that the Optune device was safe, non-investigational and effective. In addition, these trials showed that the Optune device was appropriate for this individual Enrollee's needs, specifically the treatment of recurrent glioblastoma.

Third, the use of TTFT is generally accepted by the medical community. In the 2015 version of the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology Central Nervous System Cancers guidelines, alternating electric field therapy is a treatment option suggested for glioblastoma. (Exh. 1, p. 13; Hearing testimony). This suggestion was found in a treatment guideline from a national cancer organization, not evidence based on an individual physician treating a single patient in a clinical setting. As such, this ALJ finds that TTFT treatment is generally accepted in the medical community as safe and effective for the treatment of recurrent glioblastoma.

Overall, a review of the literature available showed that the Optune device received FDA premarket approval, showing that it was safe and effective and not investigational/experimental. The use of the Optune device in a population with recurrent glioblastoma was proven effective and appropriate through a phase III clinical trial; and the use of the Optune device appears in

³<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm>

national cancer treatment guidelines for treatment of glioblastoma, showing general acceptance by the medical community. A number of commercial health plans also now cover TTFT.

The final aspect is the medical record of this specific Enrollee. A review of the medical records and hearing demonstrated that the Enrollee had already undergone surgical resection of the tumor and chemotherapy. When he began treatment with the Optune (TTFT) device, the Enrollee had exhausted other treatment options and his disease continued to recur and progress. This Enrollee had no feasible alternative pattern of care available to him to halt the progression of his disease. For the Enrollee, the preponderance of the evidence is that the TTFT therapy was medically reasonable and necessary for the treatment of his condition.

For the reasons stated above, this ALJ finds that Optune (TTFT) has been shown to be safe and effective and was medically reasonable and necessary for the treatment of this Enrollee's condition for the dates of service in question.

Conclusions of Law


This decision is **FULLY FAVORABLE** for the Appellant/Enrollee. This Administrative Law Judge decides that the Plan must pre-approve the use of the Optune device using tumor treatment field therapy (TTFT). Therefore, the Plan shall cover the related care received by the Enrollee from February 27, 2017, to March 31, 2017.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated: AUG 02 2017


Aaron R. Raff
 U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, Missouri

Appeal of:	ALJ Appeal No.: 1-7824750956
Beneficiary:	Medicare: Part B
HICN:	Before: Aaron R. Raff U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented, this Administrative Law Judge (“ALJ”) enters a **FULLY FAVORABLE** decision for this Beneficiary/Appellant, (“Beneficiary”). At issue are multiple claims involving the Optune® System and related accessories (HCPCS code E0766) the supplier (Novocure Inc., “Novocure”) billed on the following dates of service: August 24, 2017; September 24, 2017; October 24, 2017; and November 24, 2017. The hearing record establishes this Beneficiary is entitled to coverage for the durable medical equipment (“DME”) under Medicare Part B. Novocure is entitled to payment for the covered services.

Procedural History

The Beneficiary was provided with the Optune System (formally known as NovoTTF-100A System),¹ which includes an electric field generator device and disposable transducer arrays. Novocure submitted multiple claims on behalf of this Beneficiary to Noridian Healthcare Solutions, the Medicare Administrative Contractor (“Contractor”) with jurisdiction. The Contractor denied the claims initially and on redetermination. C2C Solutions, Inc., the Qualified Independent Contractor (“QIC”), issued a consolidated unfavorable reconsideration decision on July 11, 2018.

On August 22, 2018, the Office of Medicare Hearings and Appeals (“OMHA”) received this Beneficiary’s timely request for an ALJ Hearing. 42 C.F.R. § 405.1014(c). The ALJ held a hearing by telephone on October 10, 2018. The Beneficiary did not participate in the hearing but appeared through her representative, Debra Parrish (Esq.). Justin Kelly (NP, Senior Director of Health Policy with Novocure) appeared as a witness. Nurse Kelly testified under oath. Exhibits

¹ TTFT stands for tumor treatment field therapy.

1-7² were admitted into the record without objection. The ALJ carefully considered the testimony, arguments, and medical evidence.

Issues

The issues before the ALJ are those include all of the issues brought out in the initial determination, redetermination, and/or reconsideration that were not decided entirely in a party's favor and any additional issues specified in the request for hearing.

The issues are described in more detail in Section A of the Analysis.

Findings of Fact

After careful consideration of the entire record (Exhibit List attached and incorporated herein), a preponderance of the evidence establishes the following facts:

1. The Food and Drug Administration ("FDA") initially approved Novocure's Pre-Market Approval ("PMA") application for the NovoTTF-100A System on April 8, 2011. (Exh. 1, pp. 68-72). The letter states:

This device is indicated for treatment of adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme, following histologically- or radiologically confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GB after surgical and radiation options have been exhausted.

(Exh. 4, p. 68; *see also* Product Dossier, Exh. 4, p. 93).

2. The FDA expanded the PMA on October 5, 2015. (Exh. 6, pp. 1-4). The letter states:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) supplement for the Optune™ (formerly the NovoTTF-100A System). *This device is indicated as a treatment for adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme (GBM). Optune™ with temozolomide is indicated for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy.* Optune™ was previously approved in 2011 for the treatment of recurrent GBM with the following Indications for Use (IFU):

² The ALJ found good cause to admit new medical evidence as Exhibit 7. Ms. Parrish also provided a CD of various documents to support of her argument that the services at issue should be covered for this Beneficiary. The documentation includes various publications, including the FDA approvals for the Novocure's TTFT device, NCCN guidelines covering the dates of service, and presentation materials published by the American Society for Radiation Oncology ("ASTRO"). The CD is part of the record, and also select portions were printed into Exhibit 6 (most of the remaining documents are duplicates already in other exhibits).

Optune™ is indicated following histologically-or radiologically-confirmed recurrence in the supra-tentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted. We are pleased to inform you that the PMA supplement is approved. You may begin commercial distribution of the device as modified in accordance with the conditions of approval described below.

(Exh. 4, p. 68, emphasis added).

3. The National Comprehensive Cancer Network's ("NCCN") 2017 guidelines for treatment of patients newly diagnosed with Glioblastoma ("GBM") was categorized as a "1."³ (Exh. 4, pp. 26-29).
4. The Beneficiary was a 62-year-old female who turned 63 years old during the dates of service at issue.
5. The Beneficiary was diagnosed with Grade IV GBM in February 2015. (Exh. 2, p. 7; Exh. 4, p. 22).
6. The Beneficiary presented to the hospital secondary to a new onset of seizure activity on February 17, 2015. *Id.* Imaging revealed a ring-enhancing right parietal lesion. *Id.* The Beneficiary underwent resection surgery followed by chemoradiation. (Exh. 4, pp. 22, 24). The Beneficiary completed a total of 12 cycles of Temozolomide by May 2015. (Exh. 4, p. 22).
7. A physician signed the initial prescription and order form for the Optune TTFT device, and related supplies, in June 2015. (Exh. 2, p. 2).
8. An employee of Novocure filled out an Assessment of Need in July 2015. (Exh. 2, p. 3).
9. The Beneficiary started using the Optune System on August 24, 2015. (Exh. 4, p. 22).
10. The Beneficiary met with her oncologist on December 14, 2016. (Exh. 4, pp. 22-25). The oncologist indicated a November 2016 MRI revealed stable findings. (Exh. 4, p. 22). The oncologist indicated the plan of care was for the Beneficiary to continue TTFT treatment with the Optune System. (Exh. 4, p. 24).
11. The oncologist indicated the Beneficiary was 89 percent compliant with TTFT treatment. *Id.*

³ A Category 1 indication is based on high-level evidence with uniform NCCN consensus that the intervention is appropriate. See NCCN, at https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx.

12. The Beneficiary met with her oncologist on July 14, 2017. (Exh. 7, pp. 6-9). The oncologist indicated he/she reviewed a July 2017 compliance report, which confirmed the Beneficiary was using the Optune device 89 percent of the time, and experiencing only mild skin irritation. (Exh. 7, p. 6). The oncologist noted the July 10, 2017 MRI revealed no evidence of enhancing changes, edema, mass effect, or shifting compared imaging obtained three months earlier. (Exh. 7, p. 7). The oncologist indicated the plan of care was for the Beneficiary to continue TTFT treatment with the Optune System. (Exh. 7, p. 8).
13. A physician signed a second prescription and order form for the TTFT device and related supplies on August 9, 2017. (Exh. 2, pp. 1). The physician indicated the Beneficiary was diagnosed with GBM (ICD-10 diagnosis code C71.9). *Id.* The plan of care was to start (or continue) treatment on August 22, 2017. *Id.* The physician signed the order, indicating he/she believed the Optune TTFT device and accessories/supplies were medically necessary for a 6-month period. *Id.*
14. The Beneficiary met with her oncologist on October 11, 2017. (Exh. 7, pp. 10-12). The oncologist indicated he/she reviewed a September 2017 compliance report that indicated the Beneficiary was using the Optune device 87 percent of the time (and experiencing only mild skin irritation). (Exh. 7, p. 10). The oncologist indicated the plan of care was for the Beneficiary to continue TTFT treatment with the Optune System. (Exh. 7, p. 8).
15. Patient Compliance Reports document the Beneficiary compliance with the Optune® TTFT between November 2016 and May 2017. (Exh. 4, pp. 17-21). The reports indicate the Beneficiary used the device no less than 82 percent of the time. *Id.*
16. Patient Compliance Report between September and December, 2017 indicated the Beneficiary used the Optune® TTFT device between approximately 80-87 percent of the relevant times. (Exh. 7, pp. 2-5).
17. The record includes Invoices for August 24, September 24, October 24, and November 24, 2017. (Exh. 2, pp. 4-6, 16). The invoices consistently lists charges for the 1 unit of "Novo-TTF 100A Plus Transducers (TFH9000)." *Id.*
18. The record includes a copy of the Optune Service Agreement, which includes the Supply Terms for Optune, Patient Information Form for Optune, Patient Bill of Rights, and Contact Information for Questions or Complaints. (Exh. 4, pp. 1-10).
19. The hearing record includes a Patient Information and Consent form, Patient Document Acknowledgement sheet, and a Technical Review of Optune sheet. (Exh. 4, pp. 13-16). The Beneficiary signed or initialed these documents. *Id.*
20. The hearing record includes a 2-page document entitled Authorization to Release Information; Assignment of benefits; Acknowledge of Education and Training;

Acknowledgment of Receipt of Certain Forms; and Delivery Confirmation. (Exh. 4, pp. 11-12).

21. At hearing, Ms. Parrish argued the Beneficiary is entitled to coverage for the Optune System (including the arrays) since the record as a whole indicates the device was safe and effective for the treatment of GBM prior to the dates of service. (Hearing CD).
22. Ms. Parrish argued the LCD is not applicable in this case and that coverage should be based on the general coverage criteria outlined in the *Medicare Program Integrity Manual*. Medical Directors associated with one or more of CMS's Contractor had indicated the LCD is not applicable in cases that involve patients who are newly diagnosed with GBM.
23. Ms. Parrish argued the medical community supports treating GBM with TTFT. An EF-14 clinical trial was terminated at the behest of ASTRO after the results revealed higher survival rates in patients using TTFT with Temozolomide over those using only Temozolomide. TTFT with Temozolomide for GBM is categorized by the NCCN as a Category 1, indicating uniform consensus.
24. Ms. Parrish argued the fact that this Beneficiary is alive and her disease stable is further evidence that the treatment is effective. *Id.*
25. Nurse Kelly has knowledge of this Beneficiary's medical history. (Hearing testimony). She was initially diagnosed with GBM in 2015. *Id.* She initially started using the Optune System in August 2015. *Id.* She used the device continuously up to and throughout the dates of service.
26. The Beneficiary continues to carry a diagnosis of GBM, and has not been diagnosed with RGBM. *Id.*
27. Nurse Kelly is aware of the results of a MRI that had been obtained in August 2018. *Id.* The imaging confirmed the GBM remained stable. *Id.*

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (“HHS”), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (“Act”) § 1869(b)(1)(A); *see also* 42 C.F.R. § 405.1014. The Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decision of the Secretary, unless the individual/organization appeals to the Medicare Appeals Council. *Id.*

A request for hearing is timely if it is received by OMHA within 60 days after the party received the reconsideration decision, unless the individual/organization establishes good cause to extend the time to file. 42 C.F.R. §§ 405.1002(a)(1) and 405.1014(c). The appealing party is presumed to have received the QIC’s reconsideration five days after the date noted on the first page of the reconsideration, unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3).

B. Scope of Review

The ALJ considers all issues not decided entirely in the party’s favor at any prior level of review. 42 C.F.R. § 405.1032(a). The ALJ assigned to hear this matter may give notice to the parties of any other issue will be addressed at the hearing. 42 C.F.R. § 405.1032(b). The ALJ may also issue a decision on the record at the request of a party and there are no other parties who wish to appear. 42 C.F.R. § 405.1038(b). The ALJ may also issue a decision on the record on his/her own initiative if the evidence in the record supports a fully favorable finding. 42 C.F.R. § 405.1038(a).

A party may not offer new evidence for the first time at the ALJ level of review unless good cause exists. 42 C.F.R. § 405.1018(c). The party must submit a statement explaining why the evidence not previously submitted. *Id.* The ALJ will examine the statement and evidence to establish whether good cause was established. 42 C.F.R. § 405.1028(a). This restriction is not applicable to unrepresented beneficiaries or oral testimony given during the course of a hearing. 42 C.F.R. § 405.1018(d).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue and makes a decision based on the evidence, without regard to the findings made by the lower levels on the claim. 42 C.F.R. § 405.1000(d). The appealing party bears the burden of proving each element of the Medicare claim. Act §§ 1814(a)(1), 1815(b), and 1833(e); *see also* 42 C.F.R. §§ 405.1018, 405.1028, 405.1030, and 424.5(a)(6).

II. Principles of Law

A. Statutes & Regulations

The statutory authority for the Medicare program is found in Title XVIII of the Act. 42 U.S.C. § 1395 *et seq.* The Medicare program is divided in multiple parts. Medicare Part B is a voluntary insurance program that provides medical insurance benefits to “aged and disabled individuals” for services not covered under Medicare Part A (or Part D). Act § 1831. The individual must elect to enroll in the program. *Id.* The program is financed through contributions appropriated by the Federal Government in addition to premium payments. *Id.* The Secretary of the Department of Health and Human Services has the authority to promulgate regulations which define or clarify the provisions of the Act. 42 C.F.R. § 410 *et seq.*

Section 1832 of the Act establishes the scope of benefits that are provided to an eligible beneficiary under Medicare Part B. *See also* 42 CFR §§ 410.3 and 410.10. Section 1832(a)(2)(B) of the Act indicates an individual is entitled to have payment made on his/her behalf for medical and other health services furnished by a provider of services or by others under arrangement with a provider. Section 1861(s)(6) of the Act defines the term “medical and other health services” to include durable medical equipment. *See also* 42 CFR §410.36(a)(3).

Medicare coverage for DME is determined in one of three ways. The claim must be decided consistent with an applicable “National Coverage Determination” (NCD). Act § 1869(c)(3)(B)(ii)(I). If there is no applicable NCD, the decision maker is required to consider, though is not bound, by the Local Coverage Determination (“LCD”) for the geographical area at issue. Act § 1869(c)(3)(B)(ii)(II). If there is no NCD or LCD addressing the matter, the decision maker is required to decide the matter “based on applicable information, including clinical experience and medical, technical, and scientific evidence.” Act § 1869(c)(3)(B)(ii)(III); *see also* 68 Fed. Reg. 63693.

The regulations define durable medical equipment as follows:

Equipment, furnished by a supplier or a home health agency that:

- 1) Can stand repeated use.
- 2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- 3) Is primarily and customarily used to serve a medical purpose.
- 4) Generally is not useful to an individual in the absence of an illness or injury.
- 5) Is appropriate for use in the home.

42 CFR § 414.202.

Section 1834 of the Act defines the rules for payment of durable medical equipment. *See also* 42 C.F.R. §§ 410.38(g) and 414.210.

Medicare may not make a payment under Part A or Part B for anything which is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of

a malformed body member. Act § 1862(a)(1)(A); *see also* 42 C.F.R. §§ 411.15(k) and 414.200 *et seq.* A provider or supplier is responsible for providing sufficient documentation to support the services were medically necessary, the services were provided as bill, and that payment is due. Act §§ 1833(e); *see also* 42 C.F.R. § 424.5(a)(6).

In the event the services are found to be “not medically reasonable and necessary” or “custodial in nature” under Section 1862(a)(1) or (9) of the Act, Section 1879 of the Act provides for limitation on liability for Medicare payments. The regulations address how to determine if the beneficiary or provider/supplier had the requisite degree of knowledge to make them liable under Section 1879 of the Act. 42 C.F.R. § 411.400 *et seq.*; *see also HCFA Ruling 95-1*. If a beneficiary has no knowledge that the services would not be covered, but the provider/supplier of the services did, then the provider/supplier is liable and cannot seek or retain payment made by or on behalf of a beneficiary. 42 C.F.R. § 411.404. In general, the existence of a notice, manual, or community medical standard is sufficient to constitute finding the provider/supplier had notice. 42 C.F.R. § 411.406.

B. Policy and Guidance

Unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than a NCD, can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. Act § 1871(a)(2); *see also* 42 C.F.R. § 405.1060. An NCD is the Secretary’s determination on Medicare coverage for a particular item or services applied nationally. 42 C.F.R. § 405.1060(a). An ALJ is bound by the NCD and required to ensure the NCD is applied correctly when applicable. 42 C.F.R. § 405.1060(a), (b).

The Secretary has not issued an NCD specifically addressing the DME, or the related supplies, at issue in this case. CMS, *Medicare National Coverage Determinations (Internet-Only Manual Publ’n 100-03)*, ch. 1. *See* NCD § 280.1 *et seq.* regarding DME coverage in general.

CMS and its contractors are permitted to issue policy guidance describing criteria for coverage and payment of selected items and services. 42 C.F.R. § 405.1062. This guidance is located in Medicare’s manuals and local coverage determinations (“LCD”). An ALJ is not bound by the policies outlined in a manual or LCD but is required to give the guidance substantial deference when applicable. 42 C.F.R. § 405.1062(a). An ALJ may decline to follow the guidance but must explicitly explain the reason(s) why. 42 C.F.R. § 405.1062(b). The ALJ’s decision not to follow the policy applies only to the specific claim being considered and has no precedential effect on other claims. *Id.*

The Contractor had issued an LCD (and Policy Article) addressing coverage and payment guidelines for TTFT in general that is applicable to this Beneficiary’s geographical jurisdiction for the dates of service at issue. Noridian Healthcare Solutions, LLC, *Local Coverage Determination L34823: Tumor Treatment Field Therapy (TTFT) (LCD L34823)* (Oct. 2015, revised Jan. 2017). The LCD does not specific reference any ICD-10 diagnosis codes, such as GBM or recurrent GBM (“RGBM”). *Id.* The LCD merely states that “tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.” *Id.*

The *MPIM* indicates the Contractor is required to consider specific requirements when developing an LCD or, when there is no NCD and/or LCD, to make a determination on each individual claim. *MPIM (Internet-Only Manual Publ'n 100-08)*, ch. 13 § 13.3 (Jan. 2013). The decision is to be based on the medical reviewer's clinical judgement in light of the reasonable and necessary provisions outlined in Section 13.5.1. *Id.*

Reasonable and Necessary

Contractors shall describe in the draft LCD the circumstances under which the item or service is reasonable and necessary under 1862(a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
 - o Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
 - o Furnished in a setting appropriate to the patient's medical needs and condition;
 - o Ordered and furnished by qualified personnel;
 - o One that meets, but does not exceed, the patient's medical need; and
 - o At least as beneficial as an existing and available medically appropriate alternative.

There are several exceptions to the requirement that an item or service be reasonable and necessary for diagnosis or treatment of illness or injury. The exceptions appear in the full text of § 1862(a)(1).

MPIM, ch. 13 § 13.5.1; *see also Almy v. Sebelius*, 679 F.3d 297, 299 (4th Cir. 2012).

The Contractor is required to use the "strong evidence available." *MPIM*, ch. 13 § 13.7.1.

In order of preference, LCDs should be based on:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
- General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
 - o Scientific data or research studies published in peer-reviewed medical journals;
 - o Consensus of expert medical opinion (i.e., recognized authorities in the field); or
 - o Medical opinion derived from consultations with medical associations or other health care experts.

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by

sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

Id.

The *Medicare Benefits Policy Manual* ("MBPM") defines reasonableness and necessity with regard to DME specifically. *MBPM (Internet-Only Manual Publ'n 100-2)*, ch. 15, § 110 (Oct. 2003). An item classified as DME will not be covered in every instance." *MBPM*, ch. 15, § 110.1.C. The item(s) must be "necessary and reasonable for treatment of an illness or injury, or to improve the functioning of a malformed body member." *Id.* The *MBPM* states:

1 - Necessity for the Equipment

Equipment is necessary when it can be expected to make a meaningful contribution to the treatment of the patient's illness or injury or to the improvement of his or her malformed body member. In most cases the physician's prescription for the equipment and other medical information available to the DMERC will be sufficient to establish that the equipment serves this purpose.

2 - Reasonableness of the Equipment

Even though an item of DME may serve a useful medical purpose, the DMERC or intermediary must also consider to what extent, if any, it would be reasonable for the Medicare program to pay for the item prescribed. The following considerations should enter into the determination of reasonableness:

1. Would the expense of the item to the program be clearly disproportionate to the therapeutic benefits which could ordinarily be derived from use of the equipment?
2. Is the item substantially more costly than a medically appropriate and realistically feasible alternative pattern of care?
3. Does the item serve essentially the same purpose as equipment already available to the beneficiary?

3 - Payment Consistent With What is Necessary and Reasonable

Where a claim is filed for equipment containing features of an aesthetic nature or features of a medical nature which are not required by the patient's condition or where there exists a reasonably feasible and medically appropriate alternative pattern of care which is less costly than the equipment furnished, the amount payable is based on the rate for the equipment or alternative treatment which meets the patient's medical needs.

The acceptance of an assignment binds the supplier-assignee to accept the payment for the medically required equipment or service as the full charge and the supplier-assignee

cannot charge the beneficiary the differential attributable to the equipment actually furnished.

Id.

The *MPIM* identifies what documentation a supplier is required to retain for at least a 7-year period. *MPIM*, ch. 5. The supplier is required to have an order from the physician prior to delivering the DME and/or related supplies. 42 C.F.R. § 410.38; *MPIM*, ch. 5, §§ 5.2.1, 5.2.2, and 5.2.3. The supplier must obtain a detailed written prior to filing a claim. *Id.* The supplier is required to maintain proof of delivery. *MPIM*, ch. 4, § 4.26.1 and ch. 5, §§ 5.7 and 5.8.

All Medical records must be authenticated by the author. *MPIM*, ch. 3, § 3.3.2.4. The method used shall be a handwritten or electronic signature, as stamped signatures are not acceptable. *Id.*

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ANALYSIS

The Beneficiary filed a timely appeal and the amount in controversy reasonably meets the \$160 requirement. 42 C.F.R. § 405.1002. The ALJ conducted a *de novo* review of the evidence to determine if the Optune TTFT System⁴ is medically reasonable and necessary in general for the treatment of GBM. The dates of service in this case are August 24, September 24, October 24, and November 24, 2017. Thus, this general determination turns on whether the Optune TTFT System was no longer investigational and experimental in 2017 and whether it had been proven safe and effective, was widely accepted by the medical community, and appropriate for the treatment of GBM/RGBM by 2017. This general topic shall be referred to as the “Investigational and Experimental Issue.” See Section B.⁵

Second, the ALJ reviewed the specific medical reasonableness and necessity of the treatment for the Optune System for this Beneficiary. See Section C.

This decision will not address specific documentation requirement since this issue was not raised during the earlier levels of appeal. This decision will also not address liability since the services at issue are covered under Medicare Part B.

A. SUMMARY OF RESULT IN THIS SPECIFIC CASE

The ALJ has determined that the Optune System (which includes the transducer arrays) was more than investigational and experimental, and generally an acceptable form of medical treatment for GBM in 2017 for appropriate patients. The DME status of the device at issue is not contested. The medical record does contain a physician’s order for the device. The Beneficiary thus prevails on the threshold issues. The ALJ also finds in FAVOR of this Beneficiary on the merits with regard to coverage. The Optune System (which includes the insulated transducer arrays) were medically reasonable and necessary on the dates of service.

B. GENERAL NECESSITY – WAS THE OPTUNE SYSTEM ‘INVESTIGATIONAL AND EXPERIMENTAL’ FOR THE TREATMENT OF GBM IN 2017?

Optune System meets the definition of DME

In general, for an item of DME to be covered by Medicare, it must be eligible for a defined Medicare benefit category, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and meet all other applicable statutory and regulatory requirements. Act § 1862(a)(1)(A). The documentation must demonstrate the DME, and supplies, satisfy the medical reasonable and necessary standard. MPIM, ch. 5, § 5.7. The MPIM states the medical records should include information about a patient’s diagnosis and other pertinent information to substantiate medical necessity for the type

⁴ The NovoTTF-100A /Optune TTFT System is an electric field generator that uses disposable insulated transducer arrays to transmit electric waves to the desired area.

⁵ The record establishes CMS has accepted the Optune System is durable medical equipment (“DME”).

and quantity of items ordered as well as the frequency of use and replacement. *MPIM*, ch. 5, §§ 5.7 and 5.8.

A supplier is required to maintain a record of the dispensing order, the detailed written order, Certificate of Medical Necessity or DME Information Form (if applicable), and proof of delivery in addition to information related to a beneficiary's diagnosis. *MPIM*, ch. 5, § 5.8; *see also MPIM*, ch. 5, §§ 5.2 and 5.3. If the information in the patient's medical record does not adequately support the medical necessity for the item, or there is missing documentation, the supplier is liable for the cost of the item absent a valid Advance Beneficiary Notice. *MPIM*, ch. 5, §§ 5.7 and 5.8; *see also* Act § 1833(e) and 42 C.F.R. § 424.5(a)(6).

It is uncontested that the Optune System is DME that falls within a defined benefit category.⁶ CMS issued an interpretation or bulletin to this effect in July 2013. (Exh. 4, p. 67). However, the mere status that the Optune System was accepted as a piece of DME is not the primary inquiry in this case, and insufficient alone to achieve coverage.

General Medical Necessity

Evaluating Medical Necessity in General

Section 522 of the Benefits Improvement and Protection Act permits a contractor to issue a decision addressing whether and in what circumstances an item or service is covered as reasonable and necessary under Section 1862(a)(1)(A) of the Act. *MPIM*, ch. 13, §§ 13.1.3 and 13.5.1. The *MPIM* indicates the contractor "shall consider a service to be reasonable and necessary if the contractor determines that the service is:" (1) safe and effective; (2) not experimental or investigational; and (3) appropriate. *Id.* The contractor is to consider all applicable information when making a determination on a claim in those cases where there is no applicable NCD or LCD. Act § 1869(c)(3)(B)(i)(III).⁷

In this case, there was no formal guidance in the form of an NCD addressing the Optune System (and arrays) at issue on the dates of service but the Contractor had issued *LCD L34823*. LCD's must be given substantial deference, but the ALJ can decline to follow an LCD as applied to a specific Beneficiary's case with a written rationale. 42 C.F.R. § 405.1062. The relevant section of the LCD reads as follows:

For items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act §1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

Id. The LCD however includes no discussion of the required analysis outlined in the *MPIM*. The sources the Contractor reviewed do not contain any literature that was published after 2013. *Id.*

⁶ See NCD 280.1 generally.

⁷ NCD, ch. 1, § 280 *et seq.* governs DME in general. There are no provisions addressing TTFT.

The present matter involves dates of service in 2017 (four years later), and substantial change has taken place in the FDA labeling and medical literature about TTFT, which diminish the LCD's application to this specific Beneficiary's situation. The ALJ is unable to determine why the Contractor concluded TTFT was unsafe and ineffective, continued to be experimental and/or investigational, and/or inappropriate for GBM in general. *MPIM*, ch. 13 § 13.5.1. The ALJ therefore declines to follow the LCD as applied to this specific Beneficiary case (after giving the LCD substantial deference), and proceeds to consider whether the Optune System was medically reasonable and necessary for this specific Beneficiary following other available Medicare guidance.⁸ 42 C.F.R. § 405.1062.

TTFT Treatment is Safe, Effective, and Not Investigational or Experimental

The ALJ considered the hearing record and finds the Optune System to treat GBM was medically reasonable and necessary in 2017 since the device was safe, effective, and not investigational and/or experimental. It is also important to note in understanding the medical record and available literature that this matter focuses on a Beneficiary patient with initial GBM, and not recurrent-GBM (RGBM), which is only discussed in passing.

The argument and witness testimony provided on behalf of this Beneficiary focused on the 2015 supplemental PMA showing that the Optune System (with Temozolomide) was more effective in slowing down the progression of GBM in newly diagnosed patients compared to a chemotherapy agent alone.

The ALJ independently reviewed the articles in the record and finds they support this Beneficiary's position that the Optune System was safe and effective for the treatment of newly diagnosed GBM on the dates of service. (Exh. 3). Various articles initially documenting changes observed in the cell structure, animal trials followed by a Phase I human trial using TTFT. (Exh. 4; Exh. 6). The initial human clinical trial focused on RGBM.⁹

Novocure then conducted a significantly larger EF-11 clinical trial that concluded in 2012. (Exh. 6, *see European Journal of Cancer*).¹⁰ The EF-11 clinical trial enrolled a total of 237 patients with RGBM, which concluded in 2011. Of the 237 patients, 120 patients from 28 institutions over 7 countries were scheduled to receive TTFT treatment. Ninety-three of these patients completed at least 1 cycle, or 4 weeks of TTFT treatment. The remaining 117 patients were

⁸ Ms. Parrish argued in part that LCD L34823 is not applicable in this case. She stated that at least some Medical Directors have stated the LCD does not apply to cases that involve beneficiaries, such as this patient, who have been newly diagnosed with GBM. (Hearing argument). Nevertheless, because the LCD has not been formally amended yet, the ALJ considered the LCD.

⁹ See articles, *Disruption of Cancer Cell Replication by Alternating Electric Fields*, *Alternating electric fields arrest cell proliferation in animal tumor models and human brain tumors*, and *TTFields alone and in combination with chemotherapeutic agents effectively reduce the viability of MDR cell sub-lines that over-express ABC transporters*. A clinical trial involved 20 individuals, 10 of which were diagnosed with RGBM patients. See also articles, *Chemotherapeutic treatment efficacy and sensitivity are increased by adjuvant alternating electric fields*; *Tumor treating fields: concept, evidence and future*; and *NovoTTF-100A: a new treatment modality for recurrent glioblastoma*.

¹⁰ See article, *NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma; a randomised phase III trial of a novel treatment modality*, *Eur. J. Cancer* (2012) 48, 2192-2202, Roger Stupp, et al.

scheduled to receive chemotherapy treatment alone, and all but one patient completed one cycle. The overall survival rate of patients treated with TTFT was not superior but was comparable to the overall survival rate of patients treated with chemotherapy. Similarly, the FDA's pre-market approval of TTFT for RGBM in April 2011 was based on the FDA's conclusion, in its Summary of Safety and Effectiveness Data document, that "NovoTTF-100A treatment exhibits minimal toxicity, clinically comparable primary and secondary effectiveness and better quality of life compared to the chemotherapies in the control arm of the study."¹¹

Novocure subsequently conducted an EF-14 clinical trial that concluded in 2015. (Exh. 6, *see* Stupp, Roger *et al*, *Journal of the American Medical Association: Maintenance Therapy with Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma* (Dec. 2015).¹² The EF-14 clinical trial was comprised of 695 patients with GBM, concluding in 2014 at the behest of the medical community. Of the 695 patients, 466 patients received TTFT treatment with Temozolomide and 229 patients only received Temozolomide. The study revealed patients exhibited no evidence of disease progression for 7.1 months (on average) with the Optune System compared to 4 months for those who were being treated with Temozolomide alone. The clinical trial revealed higher survival rates in patients treated with the Optune System, including 13 percent after 5 years compared to 5 percent of patients who only received Temozolomide.

Thus, the ALJ finds the studies collectively indicate TTFT treatment was safe and appear to be more effective than chemotherapy alone to treat GBM. The most common side effect of the TTFT was scalp dermatitis, a relatively minor side effect which could be addressed with oral/topical steroids and adjusting the placement of the arrays.

The medical community's acceptance of the Optune System as a means of treating GBM supports this Beneficiary's contention that the device was safe and effective for GBM as early as 2015. The FDA approved Novocure's supplemental PMA in October 2015 for GBM. To date, the FDA has never withdrawn the approval, or issued any warnings.

The NCCN did not immediately add TTFT treatment to its guidelines following the 2011 FDA approval. The guidelines were initially changed to add TTFT as a treatment option for RGBM in late 2012 and for GBM in 2016. The ALJ finds the record as a whole establishes by a preponderance of the evidence that the Optune System was safe and effective for the treatment of GBM during the dates of service at issue.

In summary, multiple clinical trials evaluating the effects of the Optune System initially for RGBM and subsequently expanded to address patients newly diagnosed with GBM had concluded by 2015. The FDA approved Novocure's supplemental PMA to use the Optune System to treat patients newly diagnosed with GBM in October 2015. The ALJ finds the hearing record demonstrates as a whole that the Optune System was no longer experimental or investigational for treating GBM during the dates of service.

¹¹ FDA PMA P100348, p. 38 (April 8, 2011).

¹² *See article, NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma; a randomised phase III trial of a novel treatment modality*, *Eur. J. Cancer* (2012) 48, 2192-2202, Roger Stupp, *et al*.

Appropriateness & Sufficient Medical Community Acceptance

The hearing record as a whole demonstrates the Optune System was an appropriate treatment option for those patients newly diagnosed with GBM on the dates of service. The ALJ specifically focused on three of the listed areas: furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of GBM, whether the device was just as effective as the best practices standard, and how frequent the device was used during a given period. *MPIM*, ch. 13, § 13.5.1.

First, the hearing record does demonstrate the accepted standard of medical practice for the treatment of GBM in 2017 included the Optune System. The FDA had approved Novocure's supplemental PMA in October 2015. *Id.* The NCCN amended the guidelines for the treatment of GBM in 2016 to include TTFT for GBM. *Id.*

The ALJ is moved by the fact that the FDA initially approved Novocure's PMA application for RGBM in 2011 and subsequently for GBM in 2015. The ALJ is further moved by the fact that the NCCN changed its guidelines to add TTFT to its standard of care. The Category 1 status in effect during the date(s) of service indicates the NCCN panel members were persuaded the Optune System was a viable treatment option for GBM.

Secondly, the hearing record demonstrates the Optune System was more effective compared the best practices standard (chemotherapy as a monotherapy). Ms. Parrish argued the results of clinical studies revealed the Optune System with Temozolomide was more effective then Temozolomide alone. (Hearing argument/testimony).

The ALJ considered the arguments and testimony with the language of the *MPIM*. This ALJ finds the effectiveness of the Optune System being as good as, if not better, than chemotherapy alone with less severe side effects equates to "meaningful improvement" within the meaning of the *MPIM*. Additionally, this ALJ does not read the *MPIM* to require TTFT result in a meaningful improvement beyond established treatment options that are already covered by Medicare. *MPIM*, ch. 13, § 13.5.1. The language clearly states "at least as beneficial" as existing treatment options is sufficient, a standard which is met in this case. *Id.* Ms. Parrish presented evidence that the EF-14 clinical trial revealed individuals treated with the Optune System had a better overall survival rate at the end of years 2, 3 and 5 compared to those treated with Temozolomide alone. The overall survival rate was statistically higher for those patients treated for initial GBM with the Optune System.

The ALJ finds the Optune System (with Temozolomide) is at the very least as effective as chemotherapy alone to treat GBM, safe with less side effects, and satisfies the *MPIM* as a treatment option for GBM (when medically necessary for the specific patient).

Additionally, the ALJ considered the appropriate frequency for the Optune System with regard a patient's compliance. Ms. Parrish provided evidence of this Beneficiary's compliance leading up to and during the dates of service. (Hearing testimony; Exh. 7. pp. 2-5). The articles indicate the clinical trials involved the participants using the Options System 18 hours a day on average. (Exh. 4; Exh., 6). Novocure's Product Dossier clearly indicates "the recommended average daily use is at least 18 hours." *Id.* This ALJ finds the Optune System is appropriate for daily use, with the expectation that a patient will use it 18 hours a day on average, or roughly 75 percent of the time.

Specific Requirements Needed to Demonstrate Medical Necessity

The ALJ considered Ms. Parrish's argument, the literature provided, and Nurse Kelly's testimony when establishing the specific coverage requirements for the Optune System. The ALJ has taken judicial notice of information published by the federal agencies and the medical community, including the NCCN and ASTRO. *See also the CD provided on behalf of the Beneficiary*, Exhibit 6

The Beneficiary's burden is to prove by a preponderance of the evidence that the documentation submitted with the claim(s) satisfies six requirements. The primary argument raised is that Medicare should cover the Optune System since the FDA approved the device for a condition this Beneficiary was diagnosed with. The ALJ agrees in general with Ms. Parrish's argument and finds coverage for the Optune System is medically necessary if the factors identified in the October 2015 expanded PMA are present. Moreover, this result is consistent with the information in the Product Dossier and the NCCN guidelines in effect in 2017. (Exh. 4). The October 2015 PMA approval states in pertinent part:

This device is indicated as a treatment for adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme (GBM). Optune with temozolomide is indicated for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy.

(Exh. 6, p. 1).

The ALJ broke down the approval into five separate requirements. The requirements are as follows:

- 1) the individual must be at least 22 years old;
- 2) the individual has been diagnosed with, based on histological or radiological evidence, GBM in the supratentorial region of the brain;
- 3) the individual has undergone resection surgery (if possible);
- 4) the individual has completed chemoradiation treatment; and
- 5) the TTFT is being used in conjunction with Temozolomide (at least during the initial treatment).

These requirements are consistent with the information in the Product Dossier and the NCCN guidelines in effect in 2017. (Exh. 4).

With regard to the second (and any other impacted elements), the ALJ has required the medical record contain proof of histological or radiological evidence of GBM in the supratentorial region of the brain. This Beneficiary only needs to provide a treatment note, progress note, or supplemental statement in the medical record (a supplier statement alone is insufficient) that addresses the requirement(s).

With regard to the fifth requirement, the ALJ recognizes there are limitations to the amount of chemotherapy an individual can be safely prescribed over his/her lifetime. The published literature and hearing argument/testimony clearly indicate some individuals continue to use the device for multiple months if not multiple years. The ALJ does not read this requirement to oblige the individual continuously take Temozolomide for the entire period he/she uses the Optune System. The ALJ finds it reasonable to permit coverage for the device in those instances where a chemotherapy agent was initially prescribed and used during the initial months of treatment or that no chemotherapy agent was used since the beneficiary had completed a significant number of cycles prior to starting TTFT treatment.

The sixth and final requirement is compliance. Novocure's Product Dossier and the articles indicate the ideal treatment is for a patient to use the Optune System 18 hours a day on average. (Exh. 4). The ALJ has relied on this information when finding the medical record should demonstrate the individual used the device no less than 75 percent of the time prior to and during the dates of service.

C. SPECIFIC MEDICAL NECESSITY IN THIS CASE

The medical record establishes all six requirements are present in this specific case, and therefore this Beneficiary is entitled to coverage under Medicare Part B.

The first requirement is met. The Beneficiary was 62 years old on the first of the four dates of service.

The second requirement is met. The medical record as a whole indicates the Beneficiary was diagnosed with GBM in February 2015 after a MRI revealed a ring-enhancing lesion within the right parietal. (Exh. 2, Exh. 4, and Exh. 7).

The third and fourth requirements are met. The medical record as a whole indicates the Beneficiary underwent resection surgery in February 2015. *Id.* She subsequently underwent radiation and was prescribed a chemotherapy agent (Temozolomide), which concluded in May 2015. *Id.*

The fifth requirement is met. The treatment notes indicate the Beneficiary had already completed 12 cycles of Temozolomide. The last cycle ended in May 2015. (Exh. 4, p. 22; Exh. 7, pp. 6, 10). The medical record indicates the Optune System was prescribed after this Beneficiary had already received a significant number of chemotherapy cycles.

The sixth and final requirement is met. The compliance reports consistently document this Beneficiary used the Optune System device at least 79 percent of the time just prior to and throughout the period at issue. (Exh. 2, pp. 40; Exh. 7, pp. 2-5). The ALJ finds the Beneficiary has demonstrated by a preponderance of the evidence that the coverage requirements for the Optune System were met. The device was medically reasonable and necessary and a covered service for this Beneficiary.

For the reasons indicated above, the ALJ finds the Optune System (bundled with the insulated transducer arrays) was medically reasonable and necessary for this Beneficiary on these dates of service. The Beneficiary is entitled to coverage for the services under Medicare Part B, and Novocure is due payment.

Conclusions of Law

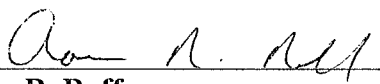
This decision is **FULLY FAVORABLE** for this Beneficiary. The ALJ concludes and decides that the monthly rental charges for the Optune System Novocure billed on August 24, 2017, September 24, 2017, October 24, 2017, and November 24, 2017 were medically reasonable and necessary. The Beneficiary is entitled to Medicare Part B coverage. Novocure is entitled to payment for the device on the respective dates of service.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated: OCT 31 2018


Aaron R. Raff
U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, Missouri

Appeal of: Novocure, Inc.	ALJ Appeal No.: 1-2668806935
Beneficiary: Estate of	Medicare: Part B
HICN:	Before: Aaron R. Raff U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented, this Administrative Law Judge (“ALJ”) enters a **FULLY FAVORABLE** decision for the Appellant, Novocure (“Appellant”). At issue is a claim involving 40 units of insulated transducer arrays (HCPCS code A9900) the Appellant billed on September 16, 2013. The hearing record does establish the Appellant is entitled to coverage for the durable medical equipment (“DME”) and related supplies under Medicare Part B. The Appellant is entitled to payment for the covered services.

Procedural History

The Appellant submitted claims for charges relating to a NovoTTF-100A System (now known as Optune® TTFT)¹ and/or a monthly supply of insulated transducer arrays to Noridian Healthcare Solutions, the Medicare Administrative Contractor (“Contractor”) with jurisdiction. The Contractor denied the claim initially and on redetermination. C2C Solutions, Inc., the Qualified Independent Contractor (“QIC”), issued an unfavorable reconsideration decision on April 21, 2014.

On May 27, 2014, the Office of Medicare Hearings and Appeals (“OMHA”) received the Appellant’s timely request for an ALJ Hearing. 42 C.F.R. § 405.1014(c). This ALJ held a pre-hearing conference by telephone on January 25, 2018, and then a consolidated hearing by telephone on April 24, 2018.² The Appellant appeared through its representative, Stephanie

¹ TTFT stands for tumor treatment field therapy.

² This ALJ initially scheduled consolidated hearings for 50 cases. The Appellant voluntarily withdrew a number of cases prior to hearing and all remaining cases received a decision or consolidated decision per beneficiary. This ALJ held a second consolidated hearing for the Appellant and CGS on April 6, 2018. This ALJ is rendering a separate decision containing the appeal numbers for each of the Beneficiaries involved in the claims.

Hales (Esq.) of Sidney Austin, LLP. Justin Kelly (NP, Senior Director of Health Policy), and Sean Dias (Case Manager) appeared as witnesses on behalf of the Appellant. The Contractor elected to participate as a non-party participant, represented by Dr. Barbara O'Neal, M.D. and Dr. Fred Manuya, M.D. Exhibits 1-6³ were admitted into the record without objection. This ALJ carefully considered the testimony, arguments, and medical evidence.

Issues

The issues before this ALJ are those include all of the issues brought out in the initial determination, redetermination, and/or reconsideration that were not decided entirely in a party's favor and any additional issues specified in the request for hearing.

The issues are described in more detail in Section A of the Analysis.

Findings of Fact

After careful consideration of the entire record (Exhibit List attached and incorporated herein), a preponderance of the evidence establishes the following facts:

1. The Food and Drug Administration ("FDA") approved the Appellant's Pre-Market Approval ("PMA") application for the NovoTTF-100A System on April 8, 2011. (Exh. 1, pp. 33-37). The letter states:

This device is indicated for treatment of adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme, following histologically- or radiologically confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GB after surgical and radiation options have been exhausted.

(Exh. 1, p. 33).

2. The National Comprehensive Cancer Network ("NCCN") updated its guidelines addressing nervous system cancers in late 2012.⁴ The NCCN indicated a physician

³ During the hearing, the hearing record was held open for specific submissions. The Appellant and Contractor were not permitted to submit additional medical records related to any of the Beneficiaries involved in this group of hearings. The Appellant provided copies of Articles discussing use of tumor treatment field therapy published in the Journal of American Medical Association in 2015, 2017, and 2018. This ALJ recognizes the articles were all published after the reconsideration decision. The Contractor submitted a pre-hearing position paper with multiple years of the NCCN guidelines. Following the hearing, the Contractor submitted additional articles and NCCN information. This ALJ finds good cause to admit the new evidence as Exhibit 6. 42 C.F.R. §§ 405.1018 and 405.1028.

⁴ See Journal of the National Comprehensive Cancer Network, at <http://www.jnccn.org/content/11/9/1114.full.pdf+html>.

should “consider alternating electric field therapy (for glioblastoma) (Category 2B).”⁵ (Journal of National Comprehensive Cancer Network, *Central Nervous Systems Cancers*, Vol. 11 No. 9, p. 1120 (Sept. 2013)).⁶

3. The Beneficiary was a 65 year-old female on the dates of service at issue. (Exh. 2, p. 4).
4. The Beneficiary was initially diagnosed with Grade IV, Glioblastoma Multiforme (“GBM”) in June of 2012, after undergoing a right temporal resection with pathology confirming GBM. (Exh. 2, p. 19).
5. Following resection, the Beneficiary was treated with radiation and Temodar from July 25, 2012, to September 16, 2012. (Exh. 2, p. 19). From August 29, 2012, to September 12, 2012, the Beneficiary received Temodar. *Id.* In January of 2013, an MRI showed progression and the Beneficiary was started on Avastin. *Id.*
6. On May 29, 2013, the Beneficiary underwent an MRI of the brain that showed enhancement in the right temporal lobe and thalamus. (Exh. 2, p. 26).
7. The Beneficiary’s last cycle of Avastin was on July 2, 2013. (Exh. 2, pp. 19-41). The physician frequently included a historical sentence in the Impression/Plan section of the visit note indicating that the Beneficiary was on Avastin monotherapy and had progression. *Id.* However, the record does not clearly show that Avastin was being used during the date of service under review. *Id.* After a thorough review of the medical records, this ALJ finds that NovoTTF-100A was used as a monotherapy during the dates of service at issue. *Id.*
8. On August 12, 2013, the Beneficiary began treatment with Novocure treatment. (Exh. 2, p. 19).
9. The Beneficiary acknowledged receipt of various products, including a NovoTTF-100A System and 40 transducer arrays, on September 16, 2013. (Exh. 2, pp. 5-7, 11).
10. The Beneficiary signed the Service Agreement, Patient Rights and Responsibilities Supplier Standards, Financial Review/Assessment, and information on how to file a complaint. (Exh. 2, pp. 10-18).
11. The physician signed a prescription and order form for the TTFT device and related supplies on August 12, 2013. (Exh. 2, pp. 1-2). The physician indicated the Beneficiary

⁵ The NCCN cited to the European Journal of Cancer, *NovoTTF-100A System versus physician’s choice chemotherapy in recurrent glioblastoma: a randomised phase III trial of novel treatment modality* (2012; 48: 2192-2202). (See also Exh. 3).

⁶ NCCN, at https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx.

A Category 2B designation is “based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate,” indicating that at least 50 percent but less than 85 percent of the panel/voting participants supported the treatment option at the time.

was diagnosed with “glioblastoma” (ICD-9 diagnosis code 191.9). *Id.* The physician signed the order, indicating he/she believed the NovoTTF-100A System and accessories/supplies continued to be medically necessary for a 6-month period. *Id.*

12. The medical record includes a Letter of Medical Necessity⁷ authored by Dr, M.D. on October 15, 2013. (Exh. 1, pp. 29-31). The physician was seeking to “initiate NovoTTF treatment” and requesting a predetermination of coverage and payment for the device and supplies. *Id.* The physician indicated the device was medically necessary since the Beneficiary had failed “systemic chemotherapy and all radiotherapy options approved for this clinical scenario” and was not a surgical candidate. *Id.*
13. The record contains an invoice and claim form listing charges for 40 units of transducer arrays at a submitted charge of \$14,000.00 and a rental of the device at \$5,500.00. (Exh. 2, pp. 3, 8-9).
14. The hearing record does not contain an Advanced Beneficiary Notice (“ABN”) and the Appellant has waived all rights to charge and collect a fee for the service(s) at issue in this case.
15. At hearing, Ms. Hales argued the Appellant is entitled to coverage for the NovoTTF-100A System and/or arrays since the device fell within a defined benefit category and had been established as safe and effective for the treatment of recurrent glioblastoma multiforme (“RGBM”) at the time of the date(s) of service. (Hearing CD).
16. Ms. Hales argued the NovoTTF-100A System should be found medically reasonable and necessary when considering the requirements found in chapter 13 of the *Medicare Policy Integrity Manual*. *Id.* The FDA approval, the results of the 2011 European clinical trial (“EF-11 clinical trial”), and NCCN’s guideline changes support finding the device in question was safe and effective. *Id.* The FDA’s approval, the results of the EF-11 clinical trial, and NCCN changes indicate the device was no longer investigational. *Id.* The device was an appropriate treatment option given the fact that the device was widely accepted and was being used in more than 100 oncology centers in 2013. *Id.*
17. Ms. Hales argued payment for the NovoTTF-100A System and supplies were not bundled until 2014. *Id.* The Appellant is entitled to separate payment for the device and/or supplies for services rendered in 2013. *Id.*
18. Nurse Kelly stated the effectiveness of the NovoTTF-100A System is comparable to that of chemotherapy alone. (Hearing testimony of Nurse Kelly). The device provides a patient with a better quality of life compared to chemotherapy. *Id.* There is no systemic

⁷ The Letter of Medical Necessity contained in all of the cases heard are identical but for the first and second to last paragraphs tailored to identify the beneficiary involved in the specific case, his/her diagnosis, and identifying the clinic he/she received his/her care from. *See also* Redetermination and Reconsideration requests. (Exh. 1).

toxicity. The most common side effect of using the device is that a patient may develop a scalp rash or irritation where the arrays are attached to his/her scalp. *Id.*

19. GBM is a rare, orphan brain cancer that affects a small portion of the population. *Id.* The initial treatment is for the patient to undergo surgical resection (when possible) followed by chemoradiation (up to dose limits) and adjuvant chemotherapy. *Id.*
20. GBM is an aggressive disease that recurs after the initial, and repeat, treatment. *Id.* A patient is diagnosed with RGBM by his/her treating physician⁸ following either a biopsy or imaging revealing the disease has returned or progressed. *Id.* Imaging, often by MRI, is more commonly used since the biopsy is a surgical procedure and most patients are not candidates for additional surgery. *Id.*
21. A patient historically is re-evaluated for further surgery, chemoradiation (up to dose limits), and chemotherapy (both initial and then maintenance). *Id.* A limited number of patients are appropriate for an additional surgery and chemoradiation treatment. *Id.* A patient typically will not survive longer than 5 months without treatment and around 12 to 14 months with treatment. *Id.*
22. The only FDA approved treatments for RGBM is the NovoTTF-100A System or possibly more Avastin⁹ (or other off-label chemo agents). *Id.* A patient's overall prognosis nevertheless remains grim. *Id.*
23. The FDA approved the Appellant's PMA application for the NovoTTF-100A System in April 2011, which is a stringent process that few devices pass. *Id.*
24. Nurse Kelly argued the TTFT treatment using the NovoTTF-100A System was a proven, established means of treating patients with RGBM prior to the date(s) of service. *Id.* The device was used in an EF-11 clinical trial involving 237 patients. *Id.* The trial revealed sufficient scientific evidence that the device was safe and as effective as chemotherapy. *Id.* The device resulted in no toxicity compared to chemotherapy. *Id.*
25. Nurse Kelly argued there was a medical consensus for the device on the date(s) of service. *Id.* The strongest literature supporting the Appellant's position is the 2012 article in the European Journal of Cancer written by Dr. Roger Stupp *et al.* *Id.* The NCCN updated the treatment guideline in late 2012 to include TTFT as an alternative treatment option for RGBM. *Id.* There were approximately 100 leading oncology centers in the United States who were certified to prescribe the device in 2013 (the number increased to hundreds more at later times). *Id.* Some private insurance companies were covering the device.¹⁰

⁸ The treating physicians may include the patient's oncologist, radiation oncologist, and/or brain surgeon.

⁹ Avastin is also known by the brand name Bevacizumab. This decision will only refer to Avastin for consistency.

¹⁰ See Aetna, at http://www.aetna.com/cpb/medical/data/800_899/0827.html#dummyLink2.

26. Nurse Kelly explained there have been favorable developments following the date(s) of service. *Id.* A second trial evaluated the use of the Optune with Temozolomide¹¹ for newly diagnosed GBM patients. *Id.* (see also Exh. 3). The FDA approved using the Optune with Temozolomide for newly diagnosed GBM in October 2015.¹² *Id.* The NCCN has since reclassified the use of TTFT as a Category 1 treatment option.¹³ *Id.*
27. Nurse Kelly argued the NovoTTF-100A System was reasonable and necessary for this specific Beneficiary. (Hearing testimony, individual case audio). The Beneficiary was diagnosed with glioblastoma in 2012. *Id.* In July of 2013, the Beneficiary was prescribed Optune for recurrent glioblastoma. *Id.* The Beneficiary's compliance with the device was 84% to 88%. *Id.*
28. The Contractor argued that a supplier is not entitled to Medicare Part B coverage merely based on the fact that an item has been classified as DME. (Hearing testimony). The Contractor and Appellant also generally discussed or agreed that later, prospective evidence was not the basis of the Contractor's review process and entitled to less weight. *Id.*
29. There was no national or local coverage decision when this claim was initially reviewed. *Id.* The claim was therefore analyzed by the Contractor under the requirements set out in Section 13.5.1 of Chapter 13 of the *Medicare Program Integrity Manual* ("MPIM"). *Id.*
30. The Contractor also argued the FDA's approved of the NovoTTF-100A System for RGBM does not entitle the Appellant to coverage. *Id.* (see also Exh. 5, p. 27; Exh. 5A, p. 12).
31. The Contractor's position is that the requirements outlined in the *MPIM* were not met. *Id.* The device did not result in meaningful improvement. *Id.* The device did not significantly prolong the patient's survival. *Id.* Any long-term side effects of using the device were unknown since the device had been used for less than 5 years. *Id.*
32. The Contractor stated the costs associated with the device and supplies were not considered when determining whether the device was medically reasonable and necessary. *Id.*

¹¹ This ALJ recognizes Temozolomide is also known by the brand name Temodar. This decision will only refer to Temozolomide for consistency.

¹² See U.S. Department of Health & Human Services, U.S. Food & Drug Administration, at <http://wayback.archive-it.org/7993/20170111141452/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm475607.htm>.

¹³ A Category 1 designation is "based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate," indicating at least 85 percent of the panel members voted in favor of the treatment option at the time.

33. The Contractor argued the literature the Appellant cited to does not support coverage for the NovoTTF-100A System. *Id.* The conclusions reached as a result of the EF-11 clinical trial should be considered invalid. *Id.* The Appellant was involved in designing the study and recruited patients that fit the hypothesis. *Id.* The study as a whole followed only 237 patients, some of which did not start treatment or dropped before the first cycle.¹⁴ *Id.*
34. The Contractor argued the effectiveness of the NovoTTF-100A System remained questionable. *Id.* The FDA panel involved in approving the device was split. *Id.* The device was approved with the chairperson's tie-breaking vote in favor of effectiveness. *Id.* The minutes indicate there was a significant debate about how effective the device was. *Id.* The NCCN did initially categorize TTFT as a Category 2B but downgraded the status to Category 3¹⁵ in 2014. *Id.* Thereafter, the status was restored to 2B in 2015, and then remained 2B through 2018.¹⁶
35. The Contractor argued the fact that an oncology center and/or physician are certified to use the device does not alone indicate general acceptance. *Id.* The certification does not mean the treatment method is being used at the center or by the physician. *Id.*
36. The Contractor explained that the trial relied on by the Appellant began as a superiority trial but was later switched to a non-inferiority trial. (Hearing testimony). Generally, a lot of emphasis is not placed on a study if halfway through the trial end points change. *Id.* The Contractor explained further that it would be interesting to see a palliative arm of the study. *Id.*

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¹⁴ The Contractor did acknowledge the small size may have been related at least in part to difficulty recruiting patients who were willing to participate in the trial.

¹⁵ A Category 3 designation is "based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate," indicating there was strong disagreement among the panel members but at least 3 panel members representing 3 different institutions voted in favor treatment option at the time.

¹⁶ Some draft/discussion comments to the NCCN in 2018 suggested there is a debate between Categories 2B and 3. The adopted guidelines continue to classify TTFT as Category 2B for the treatment of RGBM and a Category 1 treatment for newly diagnosed GBM.

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (“HHS”), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (“Act”) § 1869(b)(1)(A); *see also* 42 C.F.R. § 405.1014. The Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decision of the Secretary, unless the individual/organization appeals to the Medicare Appeals Council. *Id.*

A request for hearing is timely if it is received by OMHA within 60 days after the party received the reconsideration decision, unless the individual/organization establishes good cause to extend the time to file. 42 C.F.R. §§ 405.1002(a)(1) and 405.1014(c). The Appellant is presumed to have received the QIC’s reconsideration five days after the date noted on the first page of the reconsideration, unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3).

B. Scope of Review

The ALJ considers all issues not decided entirely in the party’s favor at any prior level of review. 42 C.F.R. § 405.1032(a). The ALJ assigned to hear this matter may give notice to the parties of any other issue will be addressed at the hearing. 42 C.F.R. § 405.1032(b). The ALJ may also issue a decision on the record at the request of a party and there are no other parties who wish to appear. 42 C.F.R. § 405.1038(b). The ALJ may also issue a decision on the record on his/her own initiative if the evidence in the record supports a fully favorable finding. 42 C.F.R. § 405.1038(a).

A party may not offer new evidence for the first time at the ALJ level of review unless good cause exists. 42 C.F.R. § 405.1018(c). The party must submit a statement explaining why the evidence not previously submitted. *Id.* The ALJ will examine the statement and evidence to establish whether good cause was established. 42 C.F.R. § 405.1028(a). This restriction is not applicable to unrepresented beneficiaries or oral testimony given during the course of a hearing. 42 C.F.R. § 405.1018(d).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue and makes a decision based on the evidence, without regard to the findings made by the lower levels on the claim. 42 C.F.R. § 405.1000(d). The Appellant bears the burden of proving each element of the Medicare claim. Act §§ 1814(a)(1), 1815(b), and 1833(e); *see also* 42 C.F.R. §§ 405.1018, 405.1028, 405.1030, and 424.5(a)(6).

II. Principles of Law

A. Statutes & Regulations

The statutory authority for the Medicare program is found in Title XVIII of the Act. 42 U.S.C. § 1395 *et. seq.* The Medicare program is divided in multiple parts. Medicare Part B is a voluntary insurance program that provides medical insurance benefits to “aged and disabled individuals” for services not covered under Medicare Part A (or Part D). Act § 1831. The individual must elect to enroll in the program. *Id.* The program is financed through contributions appropriated by the Federal Government in addition to premium payments. *Id.* The Secretary of the Department of Health and Human Services has the authority to promulgate regulations which define or clarify the provisions of the Act. 42 C.F.R. § 410 *et seq.*

Section 1832 of the Act establishes the scope of benefits that are provided to an eligible beneficiary under Medicare Part B. *See also* 42 CFR §§ 410.3 and 410.10. Section 1832(a)(2)(B) of the Act indicates an individual is entitled to have payment made on his/her behalf for medical and other health services furnished by a provider of services or by others under arrangement with a provider. Section 1861(s)(6) of the Act defines the term “medical and other health services” to include durable medical equipment. *See also* 42 CFR §410.36(a)(3).

Medicare coverage for DME is determined in one of three ways. The claim must be decided consistent with an applicable “National Coverage Determination” (NCD). Act § 1869(c)(3)(B)(ii)(I). If there is no applicable NCD, the decision maker is required to consider, though is not bound, by the Local Coverage Determination (“LCD”) for the geographical area at issue. Act § 1869(c)(3)(B)(ii)(II). If there is no NCD or LCD addressing the matter, the decision maker is required to decide the matter “based on applicable information, including clinical experience and medical, technical, and scientific evidence.” Act § 1869(c)(3)(B)(ii)(III); *see also* 68 Fed. Reg. 63693.

The regulations define durable medical equipment as follows:

Equipment, furnished by a supplier or a home health agency that:

- 1) Can stand repeated use.
- 2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- 3) Is primarily and customarily used to serve a medical purpose.
- 4) Generally is not useful to an individual in the absence of an illness or injury.
- 5) Is appropriate for use in the home.

42 CFR § 414.202.

Section 1834 of the Act defines the rules for payment of durable medical equipment. *See also* 42 C.F.R. §§ 410.38(g) and 414.210.

Medicare may not make a payment under Part A or Part B for anything which is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of

a malformed body member. Act § 1862(a)(1)(A); *see also* 42 C.F.R. §§ 411.15(k) and 414.200 *et seq.* A provider or supplier is responsible for providing sufficient documentation to support the services were medically necessary, the services were provided as bill, and that payment is due. Act §§ 1833(e); *see also* 42 C.F.R. § 424.5(a)(6).

In the event the services are found to be “not medically reasonable and necessary” or “custodial in nature” under Section 1862(a)(1) or (9) of the Act, Section 1879 of the Act provides for limitation on liability for Medicare payments. The regulations address how to determine if the beneficiary or provider/supplier had the requisite degree of knowledge to make them liable under Section 1879 of the Act. 42 C.F.R. § 411.400 *et seq.*; *see also HCFA Ruling 95-1.* If a beneficiary has no knowledge that the services would not be covered, but the provider/supplier of the services did, then the provider/supplier is liable and cannot seek or retain payment made by or on behalf of a beneficiary. 42 C.F.R. § 411.404. In general, the existence of a notice, manual, or community medical standard is sufficient to constitute finding the provider/supplier had notice. 42 C.F.R. § 411.406.

B. Policy and Guidance

Unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than a NCD, can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. Act § 1871(a)(2); *see also* 42 C.F.R. § 405.1060. An NCD is the Secretary’s determination on Medicare coverage for a particular item or services applied nationally. 42 C.F.R. § 405.1060(a). An ALJ is bound by the NCD and required to ensure the NCD is applied correctly when applicable. 42 C.F.R. § 405.1060(a), (b).

The Secretary has not issued an NCD specifically addressing the DME, or the related supplies, at issue in this case. CMS, *Medicare National Coverage Determinations (Internet-Only Manual Publ’n 100-03)*, ch. 1. *See* NCD § 280.1 *et seq.* regarding DME coverage in general.

CMS and its contractors are permitted to issue policy guidance describing criteria for coverage and payment of selected items and services. 42 C.F.R. § 405.1062. This guidance is located in Medicare’s manuals and local coverage determinations (“LCD”). An ALJ is not bound by the policies outlined in a manual or LCD but is required to give the guidance substantial deference when applicable. 42 C.F.R. § 405.1062(a). An ALJ may decline to follow the guidance but must explicitly explain the reason(s) why. 42 C.F.R. § 405.1062(b). The ALJ’s decision not to follow the policy applies only to the specific claim being considered and has no precedential effect on other claims. *Id.*

CMS and CGS Administrators had not published a LCD addressing the DME and related supplies as of the date(s) of service at issue.¹⁷

¹⁷ The Contractor did not draft an LCD addressing the NovoTTF-100A System and publish it for comments until after the date(s) of service.

The *MPIM* indicates the Contractor is required to make individual claim determinations in the absence of an NCD and LCD. *MPIM (Internet-Only Manual Publ'n 100-08)*, ch. 13 § 13.3 (Jan. 2013). The decision is to be based on the medical reviewer's clinical judgement in light of the reasonable and necessary provisions outlined in Section 13.5.1. *Id.*

Reasonable and Necessary

Contractors shall describe in the draft LCD the circumstances under which the item or service is reasonable and necessary under 1862(a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
 - o Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
 - o Furnished in a setting appropriate to the patient's medical needs and condition;
 - o Ordered and furnished by qualified personnel;
 - o One that meets, but does not exceed, the patient's medical need; and
 - o At least as beneficial as an existing and available medically appropriate alternative.

There are several exceptions to the requirement that an item or service be reasonable and necessary for diagnosis or treatment of illness or injury. The exceptions appear in the full text of § 1862(a)(1).

MPIM, ch. 13 § 13.5.1; *see also Almy v. Sebelius*, 679 F.3d 297, 299 (4th Cir. 2012).

The Contractor is required to use the "strong evidence available." *MPIM*, ch. 13 § 13.7.1.

In order of preference, LCDs should be based on:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
- General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
 - o Scientific data or research studies published in peer-reviewed medical journals;
 - o Consensus of expert medical opinion (i.e., recognized authorities in the field); or
 - o Medical opinion derived from consultations with medical associations or other health care experts.

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general

acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

Id.

The *Medicare Benefits Policy Manual* ("MBPM") defines reasonableness and necessity with regard to DME specifically. *MBPM (Internet-Only Manual Publ'n 100-2)*, ch. 15, § 110 (Oct. 2003). An item classified as DME will not be covered in every instance." *MBPM*, ch. 15, § 110.1.C. The item(s) must be "necessary and reasonable for treatment of an illness or injury, or to improve the functioning of a malformed body member." *Id.* The *MBPM* states:

1 - Necessity for the Equipment

Equipment is necessary when it can be expected to make a meaningful contribution to the treatment of the patient's illness or injury or to the improvement of his or her malformed body member. In most cases the physician's prescription for the equipment and other medical information available to the DMERC will be sufficient to establish that the equipment serves this purpose.

2 - Reasonableness of the Equipment

Even though an item of DME may serve a useful medical purpose, the DMERC or intermediary must also consider to what extent, if any, it would be reasonable for the Medicare program to pay for the item prescribed. The following considerations should enter into the determination of reasonableness:

1. Would the expense of the item to the program be clearly disproportionate to the therapeutic benefits which could ordinarily be derived from use of the equipment?
2. Is the item substantially more costly than a medically appropriate and realistically feasible alternative pattern of care?
3. Does the item serve essentially the same purpose as equipment already available to the beneficiary?

3 - Payment Consistent With What is Necessary and Reasonable

Where a claim is filed for equipment containing features of an aesthetic nature or features of a medical nature which are not required by the patient's condition or where there exists a reasonably feasible and medically appropriate alternative pattern of care which is less costly than the equipment furnished, the amount payable is based on the rate for the equipment or alternative treatment which meets the patient's medical needs.

The acceptance of an assignment binds the supplier-assignee to accept the payment for the medically required equipment or service as the full charge and the supplier-assignee cannot charge the beneficiary the differential attributable to the equipment actually furnished.

Id.

The *MPIM* identifies what documentation a supplier is required to retain for at least a 7-year period. *MPIM*, ch. 5. The supplier is required to have an order from the physician prior to delivering the DME and/or related supplies. 42 C.F.R. § 410.38; *MPIM*, ch. 5, §§ 5.2.1, 5.2.2, and 5.2.3. The supplier must obtain a detailed written prior to filing a claim. *Id.* The supplier is required to maintain proof of delivery. *MPIM*, ch. 4, § 4.26.1 and ch. 5, § 5.8.

All Medical records must be authenticated by the author. *MPIM*, ch. 3, § 3.3.2.4. The method used shall be a handwritten or electronic signature, as stamped signatures are not acceptable. *Id.*

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ANALYSIS

A. INTRODUCTION AND ISSUES

This ALJ with jurisdiction conducted a *de novo* review of the evidence to first determine if the NovoTTF-100A System¹⁸ is medically reasonable and necessary in general for the treatment of recurrent GBM (“RGBM”).¹⁹ The dates of service in this case, and all the related cases held during the consolidated hearing, involve the 2013 calendar year. Thus, this general determination turns on whether the NovoTTF-100A System was merely investigational and experimental in 2013 or if it had been proven safe and effective, was widely accepted by the medical community, and appropriate for the treatment of RGBM in 2013. This general topic shall be referred to as the “Investigational and Experimental Issue,” as it was at the prehearing conference and during the hearing, and is located in Section C.²⁰

Second, for each specific patient in this series of cases, this ALJ reviewed the specific medical reasonableness and necessity of the treatment for the Novo-TTF-100A System in Section D.

Third, some cases in the hearing group also involved additional case-specific issues, such as whether there was manufacturer pricing information in the record, whether the arrays were separately payable and coded in 2013, or whether there was proof of delivery. These specific issues will be identified and resolved on a case by case basis in Section E. In this particular case, the additional issues raised relate to the proof of delivery issue. (Exh. 1, pp. 1-7).²¹

Lastly, the discussion of any liability allocation can be found in Section F.

B. SUMMARY OF RESULT IN THIS SPECIFIC CASE

This ALJ has determined that the NovoTTF-100A System, and related transducer arrays, was more than investigational and experimental, and generally an acceptable form of last resort medical treatment for RGBM in 2013 for appropriate patients. The DME status of the device at issue is not contested. The medical record contains a physician’s order for the device and supplies, adequate proof of manufacturer pricing, and proof of delivery. The Appellant thus prevails on the threshold issues. However, in this specific matter, this ALJ was FAVORABLE on the specific merits of coverage. The NovoTTF-100A System and insulated transducer arrays were medically reasonable and necessary as applied to this Beneficiary.

¹⁸ The NovoTTF-100A System is a piece of durable medical equipment and the insulated transducer arrays are a required supplies for the system. The device is now known under the name, Optune® TTFT.

¹⁹ The term ‘progressive’ is used interchangeably with ‘recurrent’.

²⁰ As an aside, there is no question, and acceptance by CMS that the device is at least Durable Medical Equipment (DME) so that is discussed only briefly in Section C. Similarly, no NCD or LCD directly on point existed during the dates of service, and so discussion of the same is minimal and reference to sub-regulatory guidance is primary to applicable CMS Manuals.

²¹ For efficiency, this ALJ will present the QIC and Contractor’s additional reasons for denying the claim harmoniously in a joint presentation.

C. GENERAL NECESSITY – WAS THE NOVOTTF-100A SYSTEM ‘INVESTIGATIONAL AND EXPERIMENTAL’ FOR THE TREATMENT OF RGBM IN 2013?

NovoTTF-100A System meets the definition of DME (But Analysis Must Continue)

In general, for an item of DME to be covered by Medicare, it must be eligible for a defined Medicare benefit category, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and meet all other applicable statutory and regulatory requirements. Act § 1862(a)(1)(A). The documentation must demonstrate the DME, and supplies, satisfy the medical reasonable and necessary standard. *MPIM*, ch. 5, § 5.7. The *MPIM* states the medical records should include information about a patient’s diagnosis and other pertinent information to substantiate medical necessity for the type and quantity of items ordered as well as the frequency of use and replacement. *MPIM*, ch. 5, §§ 5.7 and 5.8.

A supplier is required to maintain a record of the dispensing order, the detailed written order, Certificate of Medical Necessity or DME Information Form (if applicable), and proof of delivery in addition to information related to a beneficiary’s diagnosis. *MPIM*, ch. 5, § 5.8; *see also MPIM*, ch. 5, §§ 5.2 and 5.3. If the information in the patient’s medical record does not adequately support the medical necessity for the item, or there is missing documentation, the supplier is liable for the cost of the item absent a valid Advance Beneficiary Notice. *MPIM*, ch. 5, §§ 5.7 and 5.8; *see also* Act § 1833(e) and 42 C.F.R. § 424.5(a)(6).

It is uncontested that the NovoTTF-110A System is DME that falls within a defined benefit category. CMS issued an interpretation or bulletin to this effect in July 2013.²² However, as the Contractors (and Appellant) correctly pointed out, the mere status that the NovoTTF-100A System was accepted as a piece of DME is not the primary inquiry in this case, and insufficient alone to achieve coverage.

General Medical Necessity

Evaluating Medical Necessity in General

In this case, there was no formal guidance in the form of an NCD or LCD addressing the DME (and supplies) at issue on the date(s) of service. Section 522 of the Benefits Improvement and Protection Act permits a contractor to issue a decision addressing whether and in what circumstances an item or service is covered as reasonable and necessary under Section 1862(a)(1)(A) of the Act. *MPIM*, ch. 13, §§ 13.1.3 and 13.5.1. The *MPIM* indicates the contractor “shall consider a services to be reasonable and necessary if the contractor determines that the services is:” (1) safe and effective; (2) not experimental or investigational; and (3) appropriate. *Id.* The contractor is to consider all applicable information when making a

²² See NCD 280.1 generally.

determination on a claim in those cases where there is no applicable NCD or LCD. Act § 1869(c)(3)(B)(i)(III).²³

TTFT Treatment is Safe, Effective, and Not Investigational or Experimental

This ALJ considered the hearing record and finds the Appellant's arguments with the witness testimony and publications indicate using the NovoTTF-100A System to treat RGBM was medically reasonable and necessary in 2013 since the device was safe, as effective the chemotherapy alternative, and not investigational/experimental.

The Appellant's argument and witness testimony meanwhile focused on the initial PMA showing that the NovoTTF-110A System was proven at least as good as continued/repeat chemotherapy with Avastin or other agents. The NovoTTF-100A System resulted in a substantially better quality of life given the device resulted in fewer adverse side effects. For example, the NovoTTF-110A System usually only presents a skin rash as a typical side effect compared to the well-known systemic damage chemotherapy can cause.²⁴

This ALJ independently reviewed the articles the Appellant provided and finds they support the Appellant's position that the NovoTTF-100A System is safe and effective for the treatment of RGBM. (Exh. 3). The Appellant provided this ALJ with various articles initially documenting changes observed in the cell structure, animal trials followed by a Phase I human trial with the NovoTTF-100A. (Exh. 3). The initial human clinical trial was comprised of 10 individuals diagnosed with RGBM and was successful for its purpose.²⁵

Thereafter, and more central to this case, the significantly larger EF-11 clinical trial was then held prior to the dates of service. The clinical results were published in the *European Journal of Cancer* in 2012. (Exhs. 1-3, and Hearing CD).²⁶ The EF-11 clinical trial initially comprised with 237 patients with RGBM was concluded in 2011.²⁷ Of the 237 patients, 120 patients from 28 institutions over 7 countries were scheduled to receive TTFT treatment. Ninety-three of these patients completed at least 1 cycle, or 4 weeks of TTFT treatment. The remaining 117 patients were scheduled to receive chemotherapy treatment, and all but one patient completed one cycle.

²³ NCD, ch. 1, § 280 *et seq.*, governs DME in general. There are no provisions addressing TTFT.

²⁴ Familiarity with the detailed, multi-hour general hearings are assumed, and cited *passim*. This is a mere paraphrase and not intended as a complete list of the parties/participant's respective testimony. See Findings of Facts for more details. The hearing arguments and testimony also included substantial discussions about the nature of the PMA process, the PMA vote and subsequent events. These statements were considered and are discussed below.

²⁵ See articles, *Disruption of Cancer Cell Replication by Alternating Electric Fields*, *Alternating electric fields arrest cell proliferation in animal tumor models and human brain tumors*, and *TTFields alone and in combination with chemotherapeutic agents effectively reduce the viability of MDR cell sub-lines that over-express ABC transporters*. A clinical trial involved 20 individuals, 10 of which were diagnosed with RGBM patients. See also articles, *Chemotherapeutic treatment efficacy and sensitivity are increased by adjuvant alternating electric fields*; *Tumor treating fields: concept, evidence and future*; and *NovoTTF-100A: a new treatment modality for recurrent glioblastoma*.

²⁶ See article, *NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma; a randomised phase III trial of a novel treatment modality*, *Eur. J. Cancer* (2012) 48, 2192-2202, Roger Stupp, *et al.*

²⁷ One article does indicate 8 percent of the patients reportedly had a history of a lower grade glioma prior to being diagnosed with RGBM.

The overall survival rate of patients treated with TTFT was not superior but was comparable to the overall survival rate of patients treated with chemotherapy. Similarly, the FDA's pre-market approval of TTFT for RGBM in April 2011 was based on the FDA's conclusion, in its Summary of Safety and Effectiveness Data document, that "NovoTTF-100A treatment exhibits minimal toxicity, clinically comparable primary and secondary effectiveness and better quality of life compared to the chemotherapies in the control arm of the study."²⁸

Moving on to the hard data, the EF-11 clinical trial indicated 20 percent of patients from each treatment group were alive after 1 year. The results dropped to eight percent of TTFT patients alive at the end of two years in contrast to five percent of patients treated with chemotherapy. The results fell to four percent and one percent at the end of year three respectively.²⁹

Thus, this ALJ finds the studies collectively indicate TTFT treatment was safe and at least as effective as chemotherapy to treat RGBM. The most common side effect of the TTFT was scalp dermatitis, a relatively minor side effect which could be addressed with steroids and adjusting the placement of the arrays. Another theoretical side effect of the TTFT could be a neurological disorder, but this did not feature in the record(s) or unduly concern the FDA, and most neurological deterioration would be logically related to the underlying RGBM.

The medical community's acceptance of the NovoTTF-100A System as a means of treating RGBM supports the Appellant's argument that the device was safe and effective in 2013. The FDA approved the Appellant's PMA in April 2011 for RGBM. This ALJ recognizes the panel of 12 physicians were split 6-6 on whether the device was effective.³⁰ The chairperson's vote resulted in the panels' ultimate recommendation. The FDA presumably at least in part relied on the recommendation when it approved the PMA. To date, the FDA has never withdrew the approval, or issued any warnings.

The NCCN did not immediately add TTFT treatment to its guidelines in 2011. The guidelines were changed to add TTFT as a treatment option in late 2012, or more than a year after the FDA's approval. This ALJ finds the Appellant has established by a preponderance of the evidence indicates the NovoTTF-100A System was safe and effective for the treatment of RGBM.

This ALJ considered the testimony offered by the Contractor. The Contractor's testimony focused on the effectiveness of the NovoTTF-100A System. The Contractor raised multiple concerns about how the EF11 study (and the initial study) were conducted. In part, the Contractor thought the *n* value, or number of participants, of the study arms were relatively small. The EF-11 clinical trial was only comprised of 237 total participants, of which 120 of those participants were scheduled to receive TTFT monotherapy. Only 93 of the original 120

²⁸ FDA PMA P100348, p. 38 (April 8, 2011).

²⁹ This ALJ did not focus on any mortality difference because the Appellant did not argue this point. The mean survival rate was possibly higher in those patients treated with TTFT as opposed to chemotherapy with respect to those RGBM patients in whom Avastin failed (which was not the direct focus of the EF11 study).

³⁰ The panel voted unanimously that the device was safe. The panel ultimately recommended the NovoTTF-100A with a 7-3 vote (two members abstained from voting).

participants started and completed 4 weeks of treatment, or one cycle. Additionally, the EF11 trial was initially slated as a superiority study before it was switched to a non-inferiority study, and the Contractor questioned the lack of a palliative arm in the EF11 trial. However, the Contractor did not contend there were any safety concerns with using TTFT or disagree that TTFT was systemically gentler than chemotherapy for the patient.

The Contractor's witnesses raised reasonable and thoughtful points, but this ALJ thinks the Appellant's case (and burden of proof) is strong enough, e.g. a civil preponderance of the evidence, to rebut or survive those concerns. In part, this ALJ does not agree with the Contractors' argument that the results should be considered invalid merely because the EF-11 clinical trial consisted of only 237 patients split into 2 arms. GBM is an aggressive, fatal orphan disease that only affects a small fraction of the population. About 10,000 individuals are diagnosed with GBM each year. An "n" value greater than 30, and even 60 and 90, appears sufficient to provide statistical evidence that using the NovoTTF-100A system was non-inferior to chemotherapy.³¹ Furthermore, 93 patients in the TTFT arm that completed at least one cycle represented a little more than 2.5 percent of individuals diagnosed with GBM each year. The population used was significant given the aggressive nature of the disease and high mortality rate.

In addition, the fact that physicians associated with the Appellant were involved in the EF-11 clinical trial does not negate or diminish the ultimate findings. The hearing record suggests the NovoTTF-100A System was the only TTFT device being developed at the time. It is reasonable the Appellant would maintain some degree of involvement in the EF-11 clinical trial (and subsequent trials) to ensure the device was being used properly to achieve the most accurate results, and because of the linked practical reality of needing manufacturer/developer involvement when testing a piece of DME.

Finally, the fact that the EF-11 clinical trial was converted from a superiority study to non-inferiority study with no palliative arm does not suggest the results should be considered unreliable. The decision to change was sufficient since it afforded the participants greater safety and comfort. Entitled to heavy weight as well, is that the FDA, through the PMA process, actually directed the Appellant to change to a non-inferiority study for the best interests of the patients. The use of a palliative arm would also have been impractical and ethically challenging given the diagnosis. It would likely have been difficult to recruit a large number of RGBM patients willing to only accept hospice care.

This ALJ recognizes the Appellant and Contractor are in agreement that the NovoTTF-100A System does provide a patient with a higher quality of life ("QOL") and fewer side effects compared to chemotherapy. A patient's pursuit for medical-related QOL is a meritorious clinical goal, and a highly individual choice. This result dove-tails with this ALJ's ultimate determination that the NovoTTF-100A System is non-inferior to chemotherapy while offering a

³¹ This ALJ finds the size of the sample reasonable since GBM is an orphan disease. This ALJ agrees with the Appellant's argument that it would be unreasonable to require a larger study typical for common diagnoses involving millions of potential patients, such as in cardiac disease and related intervention procedures, stroke, diabetes mellitus and chronic obstructive pulmonary disease.

substantially higher QOL. The device is covered as a last resort treatment option for appropriate individuals diagnosed with RGBM for whom the device meets the statutory structure of reasonable and necessary as outlined under Medicare Part B.

In summary, multiple clinical trials evaluating the effects of the NovoTTF-100A System on patients with RGBM had concluded by 2011. The FDA approved the Appellant's PMA to use the NovoTTF-100A System to treat patients with RGBM. This ALJ finds the hearing record demonstrates as a whole that the NovoTTF-100A System was no longer experimental or investigational for treating RGBM.

However, discussed in more detail below, this ALJ rejects expanding or limiting coverage based on events that occurred after 2013. One of the Appellant's arguments is that the NovoTTF-100A System is appropriate for *other* diagnosis. The FDA, and NCCN, has since expanded the use of the Optune as part of the frontline treatment after a patient is initially diagnosed with GBM. Some of the Appellant's claims indicate the NovoTTF-100A System was prescribed to treat other central nervous system cancers. The Appellant has not provided evidence the medical community supported a broader use for these additional diagnoses in 2013. Similarly, this ALJ has not disallowed coverage based on the LCD published after the date(s) of service.

Appropriateness & Sufficient Medical Community Acceptance

The hearing record as a whole demonstrates the NovoTTF-100A System was an appropriate treatment option for RGBM on the date(s) of service. This ALJ specifically focused on three of the listed areas: furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of RGBM, whether the device was just as effective as the best practices standard, and how frequent the device was used during a given period. *MPIM*, ch. 13, § 13.5.1.

First, the hearing record does demonstrate the accepted standard of medical practice for the treatment of RGBM in 2013 included the NovoTTF-100A System. The Appellant argued the 12-person panel convened by the FDA unanimously voted the device was safe and half of the panel was persuaded that the device was effective. (Hearing testimony). The FDA considered the panel's recommendation when it approved the Appellant's PMA. *Id.* The NCCN amended the guidelines for the treatment of RGBM in late 2012 to include TTFT. *Id.* Commercial insurance companies were starting to cover the device for RGBM. *Id.* As of 2013, about 100 oncology centers were certified to prescribe the device. *Id.*

The Contractor argued the NovoTTF-100A System was not the accepted standard of medical practice. The FDA's approval of the device does not mean the device is covered under Medicare. *Id.* One cannot conclude that because a center is certified that the physicians associated with that center are prescribing the device. *Id.* The NCCN subsequently downgraded the category to Category 3 in 2014 (before raising it back to 2B in 2015). *Id.* The Contractor located no published policies that indicated a commercial insurance provider was covering the device when it initially evaluated the claim. *Id.*

This ALJ is moved by the fact that the FDA approved the Appellant's PMA application in 2011, and had been in effect for nearly two years before the date(s) of service. This ALJ is further

moved by the fact that the NCCN changed its guidelines. The Category 2B status in effect during the date(s) of service indicates that no less than half the NCCN panel members were persuaded the NovoTTF-100A System was a treatment option for RGBM. The NCCN cited to the FDA approval and EF-11 clinical trial. "Similar survival was observed in the arms, and TTF therapy was associated with lower toxicity and improved quality of life." The NCCN's recommendation in 2013 for RGBM reads:

Patients should be followed closely with serial MRI scans (at 2-6 weeks post-RT, then every 2-4 months for 2-3 years, then less frequently) after the completion of RT. Because RT can produce additional BBB dysfunction, corticosteroid requirements may actually increase therefore, scan may appear worse during the first 3 months after completion of RT, even though no actual tumor progression is present. Early MRI scans allow for appropriate titration of corticosteroid doses, depending on the extent of mass effect and brain edema. Later scans are used to identify tumor recurrence. Early detection of recurrence is warranted, because local and systemic treatment options are available for patients with recurrent disease. However MR spectroscopy, MR perfusion, or PET can be considered to rule out radiation-induced necrosis or "pseudoprogression."

Management of recurrent tumors depends on the extent of disease and patient condition. For local recurrence, repeat resection, with or without wafer placement in the surgical bed, can be performed if possible. After reresection, or if the local recurrence is unresectable, patients with poor PS should undergo palliative/best supportive care without further active treatment. If PS is favorable, systemic chemotherapy may be administered (especially for anaplastic oligodendroglomas); reirradiation is a category 2B option to consider if prior radiation procedures a good/durable response. Patients with recurrent glioblastoma may also consider alternating electric field therapy (category 2B). In the case of diffuse or multiple recurring lesions, the options are: 1) palliative/best supportive care for patients with poor POS; 2) systemic chemotherapy; 3) surgery to relieve mass effect; or 4) consider alternating electric field therapy for glioblastomas (category 2B).

All patients should receive best supportive care.

Furthermore, some commercial insurance companies were starting to cover the NovoTTF-100A System for RGBM as of the date(s) of service. Aetna began covering the device on March 19, 2013. Humana started covering the device the following a month. This ALJ finds the Appellant has persuasively demonstrated by a preponderance of the evidence that the NovoTTF-100A System had been accepted by the medical community as a treatment option for RGBM.

Secondly, the hearing record demonstrates the NovoTTF-100A System was at least as effective as the best practices standard, or chemotherapy. The Appellant argued the results of clinical studies revealed the NovoTTF-100A System was as effective as chemotherapy. (Hearing argument/testimony). The device resulted in less physical adverse symptoms compared to chemotherapy. *Id.*

This ALJ considered the arguments and testimony with the language of the *MPIM*. The effectiveness of the NovoTTF-100A System being as good as chemotherapy with less severe side effects is "meaningful improvement" within the meaning of the *MPIM*. Additionally, this ALJ does not read the *MPIM* to require TTFT result in a meaningful improvement beyond

established treatment options that are already covered by Medicare. *MPIM*, ch. 13, § 13.5.1. The language clearly states “at least as beneficial” as existing treatment options is sufficient, a standard which is met. *Id.* The Appellant has presented evidence that the EF-11 clinical trial revealed individuals treated with the NovoTTF-100A System had the same overall survival rate at the end of year 1 as those treated with chemotherapy. The overall survival rate at the end of years 2 and 3 was higher for those patients treated with the NovoTTF-100A System compared to chemotherapy.

This ALJ finds the Appellant has demonstrated by a preponderance of the evidence that the NovoTTF-100A System is at the very least as effective as chemotherapy to treat RGBM, safe and with less side effects, and satisfies the *MPIM* as a treatment option for RGBM (when medically necessary for the specific patient).

Additionally, this ALJ considered the appropriate frequency for the NovoTTF-100A System with regard a patient’s compliance. This issue was not specifically addressed during the global argument/testimony. (Hearing testimony). Ms. Hales’ statements and Nurse Kelly’s testimony addressed each of the Beneficiaries’ compliance when summarizing the specifics of each case. (Hearing testimony, individual case audio). The articles indicate the clinical trials involved the participants using the NovoTTF-100A System 18 hours a day on average. (Exh. 3). The Appellant’s Product Dossier clearly indicates “the recommended average daily use is at least 18 hours.” *Id.* This ALJ finds the NovoTTF-100A System is appropriate for daily use, with the expectation that a patient will use it 18 hours a day on average, or roughly 75 percent of the time.

Changes Following the Date(s) of Service Considered but Given Much Less Weight

There have been significant changes related to the NovoTTF-100A System since 2013. CMS assigned the NovoTTF-100A System a payment classification designation effective on January 1, 2014. The Appellant had billed the NovoTTF-100A System under miscellaneous HCPCS code E1399 and the insulated transducer arrays under miscellaneous supply HCPCS codes A9900 and A9999. CMS assigned HCPCS codes E0766 and A4555 to the device and arrays respectively. Payment for both the device and arrays would be bundled under E0766.

The FDA expanded its approval of the Optune, the second generation of the NovoTTF-100A System. The Appellant filed a supplement PMA application on April 10, 2015. The FDA approved the PMA on October 5, 2015. The FDA’s approval permitted using the Optune with Temozolomide “for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy.”

The NCCN has updated the guidelines related to RGBM on multiple occasions. The category was initially downgraded in 2014 to a “3,” indicating there was major disagreement that the intervention was appropriate.³² The use of TTFT was upgraded back to Category 2B around April 2015. The use of TTFT remains at a Category 2B for RGBM while the treatment option is a Category 1 for newly diagnosed GBM.

³² The change may reflect the consensus of those on the panel at the time.

A number of JAMA articles³³ in 2015, 2017 and 2018, in part reporting on the EF-14 study, have also emerged that support in randomized clinical trials, that TTFT (plus Temozolomide) is preferable to Temozolomide alone as a therapy for newly diagnosed glioblastoma. However, this ALJ does not think the JAMA articles change the central analysis or result in this case given the RGBM context.

Meanwhile, the Contractors collectively issued a local coverage determination, *LCD L34823*, in October 2015. *Local Coverage Determination L34823: Tumor Treatment Field Therapy (LCD L34823)*. The LCD indicates that tumor treatment field therapy “will be denied as not reasonable and necessary.” *Id.* The LCD includes no discussion of the analysis outlined in the *MPIM*. *Id.* The comments and responses suggest the decision not to cover the DME was because: 1) the FDA panel was evenly split on the question of efficacy with the chairperson’s vote breaking the tie; 2) the NCCN’s categorization of 2B indicated there was a consensus but the consensus was not uniform; and 3) the Compendia’s failure to include a narrative discussing the 2B category indicates those items do not fit Medicare’s definition of “generally medically accepted” category. *Id.*

This ALJ duly considered the changes that occurred after the date(s) of service but afforded the information little weight. This ALJ recognizes the FDA did broaden the PMA to use TTFT for individuals newly diagnosed with GBM, which is not at issue in the cases before this ALJ. The Contractor issued the initial version of the LCD days before the October 2015 approval. The LCD has been revised but continues to deny coverage for TTFT without discussing why the device is not medically reasonable and necessary in any circumstance while commercial insurance companies permit coverage in certain circumstances. Notably, this ALJ reviewed the sources the Contractors considered and found the FDA’s 2015 approval of the Appellant’s supplemental PMA was not considered. The Contractor has not cited to more recent publications.

Nevertheless, these events occurred following the date(s) of service and this ALJ finds it would be inappropriate to decide these cases prospectively. This ALJ focused on the information available on the date(s) of service when determining the use of the NovoTTF-100A System was medically reasonable and necessary for appropriate patients (addressed previously).

Specific Requirements Needed to Demonstrate Medical Necessity

This ALJ considered the Appellant’s arguments, the literature the Appellant provided, and the witnesses’ testimony when establishing the specific requirements for coverage of the NovoTTF-100A System and/or insulated transducer arrays. This ALJ has taken judicial notice of information published by the federal agencies and the NCCN.

The Appellant’s burden is to prove by a preponderance of the evidence that the documentation submitted with the claim(s) satisfies six requirements. The Appellant’s basic argument is that Medicare should cover the NovoTTF-100A System since the FDA approved the device prior to the date of service. This ALJ agrees in general with the Appellant’s argument and finds coverage for the NovoTTF-100A System is medically necessary if the factors identified in the April 2011

³³ The Journal of the American Medical Association.

PMA are present. Moreover, this result is consistent with the information in the Product Dossier and the NCCN guidelines in effect in 2013. (Exh. 3; Exh. 6). However, to the degree, if any, that the Appellant might contend this case (involving older dates of service and before subsequent broadening modifications to the FDA approval or NCCN guidelines) would allow an approval broader than the April 2011 PMA, this ALJ does not reach that far for these dates of service. The April 2011 PMA approval states in pertinent part:

This device is indicated for treatment of adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme, following histologically- or radiologically confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GB after surgical and radiation options have been exhausted.

(Exh. 1, p. 33).

This ALJ finds the approval itself appears to contain five separate requirements. The requirements are as follows:

- 1) the individual must be at least 22 years old;
- 2) the individual's medical history includes a diagnosis of GBM;
- 3) there is histological or radiological evidence of RGBM in the supratentorial region of the brain after the individual received chemotherapy;
- 4) the individual is not a candidate for further surgery or radiation; and
- 5) the TTFT is being used as a monotherapy.

These requirements are also consistent with the information in the Product Dossier and the NCCN guidelines in effect in 2013. (Exh. 3; Exh. 6).

With regard to the third (and any other impacted elements), this ALJ has required the medical record contain proof of histological or radiological evidence of RGBM in the supratentorial region of the brain after an individual has received chemotherapy. However, this ALJ has permitted some flexibility with regard to how this proof is documented. This ALJ will not require the medical record contain the actual imaging report that revealed recurrence in the supratentorial region of a patient's brain following chemotherapy. The Appellant only needs to provide a treatment note, progress note, or supplemental statement in the medical record (a supplier statement alone is insufficient) that addresses the findings.

This ALJ recognizes there might be instances where the medical record indicates a patient received Avastin (or a similar chemotherapy) while he/she was prescribed and using the NovoTTF-100A System. Avastin is the only other FDA approved treatment for RGBM. It is reasonable a physician may recommend and a patient elects to complete his/her then-current cycle of chemotherapy while he/she begins using the NovoTTF-100A System. This ALJ recognizes, as outlined in the April 2011 FDA PMA, the device is intended to be a monotherapy to treat RGBM. This ALJ will permit coverage for the device in those instances where the chemotherapy was started prior to a physician's order for the device and the chemotherapy is stopped at the end of the. Coverage will be denied if the medical record suggests the two are

being used a polytherapy, i.e. an additional cycle is started or chemotherapy is added to a patient's treatment regimen at the same time or after the physician ordered the device.

The sixth and final requirement is compliance. The Appellant's Product Dossier and the articles indicate the ideal treatment is for a patient to use the NovoTTF-100A System 18 hours a day on average. (Exh. 3). This ALJ has relied on this information when finding the medical record should demonstrate a patient used the device about 75 percent of the time prior to and/or during the dates of service. The medical record must specifically address a patient's compliance prior to and/or during the dates of service but some oral testimony may be used to explain or round out the data. However, oral testimony alone is insufficient because it does not comply with the *MPIM*. *MPIM*, ch. 5, §§ 5.7 and 5.8. Additionally, this ALJ recognizes there were instances where a patient's compliance was slightly less than 75 percent, but fluctuated. This ALJ reviewed the medical record and considered the oral testimony on a case-by-case basis.

D. SPECIFIC MEDICAL NECESSITY IN THIS CASE

The medical record establishes all six requirements are present in this specific case, and therefore the Appellant is entitled to coverage in this specific case.

The first requirement is met. This Beneficiary was 65 years old on the date(s) of service. (Exh. 2, p. 19).

The second requirement is met. The medical record does not include a copy of the pathology report; however, the physician noted that the Beneficiary underwent a right temporal resection on June 19, 2012, and that the pathology confirmed GBM. (Exh. 2, p. 19).

The third requirement is met. The medical record as a whole describes this Beneficiary's past treatment regimen included a chemotherapy agent. (Exh. 2). On May 29, 2013, the Beneficiary underwent an MRI of the brain that showed enhancement in the right temporal lobe and thalamus. (Exh. 2, p. 26). Therefore, the Beneficiary had recurrent glioblastoma in the supratentorial region of the brain

The fourth requirement is met. This ALJ relied on the physician's attestation in the Letter of Medical Necessity that this Beneficiary was not a candidate for additional surgery. (Exh. 1, pp. 29-31). Radiotherapy was considered but determined not to be a viable treatment option at the time. *Id.* The statement is consistent with the MRI findings. (Exh. 2, p. 26).

The fifth requirement is met. The medical record documents that the Beneficiary had exhausted treatment options other than the NovoTTF-100A system. (Exh. 2). This ALJ reviewed the medical record closely and it did not indicate that the Beneficiary was using Avastin (or other treatment) concurrently with the NovoTTF-100A System. (Exh. 2). This ALJ thus finds that the medical record indicates the NovoTTF-100A System was prescribed and this Beneficiary used it as a monotherapy to treat the RGBM.

The sixth and final requirement is met. At hearing, the Appellant testified that the Beneficiary's compliance was 84% to 88% for the date of service at issue. (Hearing testimony). The physician

documented in the medical record that the Beneficiary had greater than 88% compliance with the device. (Exh. 2, p. 21). This ALJ finds the Appellant has established by a preponderance of the evidence that the coverage requirements for the NovoTTF-100A System were met.

Because the Appellant is entitled to coverage for the NovoTTF-100A System, the Appellant is also entitled to coverage for the accessories and/or supplies related to the NovoTTF-100A System. This ALJ finds the insulated transducer arrays are covered.

For the reasons indicated above, this ALJ finds the NovoTTF-100A System was medically reasonable and necessary for this Beneficiary on the date(s) of service. The insulated transducer arrays were also medically reasonable and necessary. The Appellant is entitled to coverage and reimbursement for these services under Medicare Part B.

E. OTHER ISSUES RELATED TO PAYMENT AND/OR DOCUMENTATION

The Medicare Administrative Contractor determined that there was not valid proof of delivery. (Exh. 1, p. 19). However, the Qualified Independent Contractor determined that the documentation did include valid proof of delivery. (Exh. 1, p. 4). This ALJ agrees and finds that there was valid proof of delivery and does not discuss this issue further.

The Appellant prevailed on this additional issue, and on coverage in general (see previous Sections).

F. LIMITATION OF LIABILITY

There is no issue regarding liability since the services at issue were medically reasonable and necessary.

Conclusions of Law


This decision is **FULLY FAVORABLE** for the Appellant. The 40 units of insulated transducer arrays (HCPCS code A9900) the Appellant billed on September 16, 2013, were medically reasonable and necessary. The Appellant is entitled to Medicare Part B coverage and payment for the DME and supplies on the respective dates of service.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated: JUL 18 2018



Aaron R. Raff
U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, Missouri

Appeal of: Novocure, Inc.	ALJ Appeal No.: 1-2800229350
Beneficiary: Estate of	Medicare: Part B
HICN:	Before: Aaron R. Raff U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented, this Administrative Law Judge (“ALJ”) enters a **FULLY FAVORABLE** decision for the Appellant, Novocure (“Appellant”). At issue are multiple claims involving the NovoTTF-100A System (HCPCS code E1399) or 40 units of insulated transducer arrays (HCPCS code A9900) the Appellant billed on the following dates of service: March 21, 2013; May 8, 2013; and July 3, 2013. The hearing record does establish the Appellant is entitled to coverage for the durable medical equipment (“DME”) and related supplies under Medicare Part B. The Appellant is entitled to payment for the covered services.

Procedural History

The Appellant submitted claims for charges relating to a NovoTTF-100A System (now known as Optune® TTFT)¹ and/or a monthly supply of insulated transducer arrays to CGS Administrators, LLC, the Medicare Administrative Contractor (“Contractor”) with jurisdiction. The Contractor denied the claim initially and on redetermination. C2C Solutions, Inc., the Qualified Independent Contractor (“QIC”), issued an unfavorable reconsideration decision on July 9, 2014.

On August 15, 2014, the Office of Medicare Hearings and Appeals (“OMHA”) received the Appellant’s timely request for an ALJ Hearing. 42 C.F.R. § 405.1014(c). This ALJ held a pre-hearing conference by telephone on January 25, 2018, and then a consolidated hearing by telephone on April 4, 2018.² The Appellant appeared through its representative, Stephanie Hales

¹ TTFT stands for tumor treatment field therapy.

² This ALJ initially scheduled consolidated hearings for 51 cases. The Appellant voluntarily withdrew 35 of the cases prior to the hearing.

(Esq.) of Sidney Austin, LLP. Justin Kelly (NP, Senior Director of Health Policy) and Dan McCoy (Case Management Manager) appeared as witnesses on behalf of the Appellant. The Contractor elected to participate as a non-party participant, represented by Drs. Doran Edwards (MD) and Robert Hoover (MD). Nurse Kelly and Drs. Edwards and Hoover testified under oath. Exhibits 1-6³ were admitted into the record without objection. This ALJ carefully considered the testimony, arguments, and medical evidence.

Issues

The issues before this ALJ are those include all of the issues brought out in the initial determination, redetermination, and/or reconsideration that were not decided entirely in a party's favor and any additional issues specified in the request for hearing.

The issues are described in more detail in Section A of the Analysis.

Findings of Fact

After careful consideration of the entire record (Exhibit List attached and incorporated herein), a preponderance of the evidence establishes the following facts:

1. The Food and Drug Administration ("FDA") approved the Appellant's Pre-Market Approval ("PMA") application for the NovoTTF-100A System on April 8, 2011. (Exh. 1, pp. 38-42). The letter states:

This device is indicated for treatment of adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme, following histologically- or radiologically confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GB after surgical and radiation options have been exhausted.

(Exh. 1, p. 38).

This ALJ held a second consolidated hearing for 14 cases regarding the Appellant and Noridian Healthcare Solutions on April 23, 2018. This ALJ is rendering a separate decision containing 1-3 appeal numbers for each of the Beneficiaries involved in the claims.

³ During the hearing, the hearing record was held open for specific submissions. The Appellant and Contractor were not permitted to submit additional medical records related to any of the Beneficiaries involved in this group of hearings. This ALJ specifically requested the Appellant provide copies of Articles discussing use of tumor treatment field therapy published in the Journal of American Medical Association in 2015, 2017, and 2018. This ALJ recognizes the articles were all published after the reconsideration decision. This ALJ finds good cause to admit the new evidence as Exhibit 6. 42 C.F.R. §§ 405.1018 and 405.1028.

The Contractor was provided the opportunity to submit a copy of the minutes dismissing the FDA's pre-market approval of the NovoTTF-100A. The Contractor did not provide a copy within the requested timeframe, or before this ALJ issued this decision (albeit the testimony well covered the topic).

2. The National Comprehensive Cancer Network (“NCCN”) updated its guidelines addressing nervous system cancers in late 2012.⁴ The NCCN indicated a physician should “consider alternating electric field therapy (for glioblastoma) (Category 2B).”⁵ (Journal of National Comprehensive Cancer Network, *Central Nervous Systems Cancers*, Vol. 11 No. 9, p. 1120 (Sept. 2013)).⁶
3. The Beneficiary was a 65-year-old female on the dates of service at issue.
4. The Beneficiary was initially diagnosed with Grade IV, Glioblastoma Multiforme (“GBM”) in May 2011. (Exh. 2).
5. The Beneficiary initially underwent a stereotactic biopsy after a CT revealed a left parietal lesion in May 2011. (Exh. 2, p. 49). The Beneficiary underwent resection surgery in July 2011 after imaging confirmed the multifocal lesion had combined into a single lesion. *Id.* The Beneficiary received glatiramer acetate followed by chemoradiation. *Id.* The Beneficiary was started on a maintenance dose of Temodar but this was discontinued after she developed Stevens-Johnson syndrome. *Id.*
6. The Beneficiary met with an oncologist on September 5, 2012. (Exh. 6, p. 1). The oncologist indicated then-recent imaging suggested the disease was stable and recommended observation until the disease progressed. *Id.* The Beneficiary was reportedly considering multiple interventions, including intra-arterial bevacizumab. *Id.* The Beneficiary requested the NovoTTF-100A System. *Id.*
7. The Beneficiary and her husband received instruction on how to setup and use the NovoTTF-100A System on September 21, 2012. (Exh. 2, pp. 35-39).
8. The Beneficiary acknowledged receipt of various products, including a NovoTTF-100A System and 40 transducer arrays, on September 21, 2012. (Exh. 2, pp. 21-22).
9. The Beneficiary signed the Service Agreement, Patient Rights and Responsibilities Supplier Standards, Financial Review/Assessment, and information on how to file a complaint. (Exh. 2, pp. 20-34).

⁴ See Journal of the National Comprehensive Cancer Network, at <http://www.nccn.org/content/11/9/1114.full.pdf+html>.

⁵ The NCCN cited to the European Journal of Cancer, *NovoTTF-100A System versus physician's choice chemotherapy in recurrent glioblastoma: a randomised phase III trial of novel treatment modality* (2012; 48: 2192-2202). (See also Exh. 3).

⁶ NCCN, at https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx.

A Category 2B designation is “based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate,” indicating that at least 50 percent but less than 85 percent of the panel/voting participants supported the treatment option at the time.

10. The Beneficiary met with her physician on December 18, 2012. (Exh. 2, pp. 49-52). The treatment note indicated the Beneficiary was using the NovoTTF-100A System. (Exh. 2, p. 49; *see also* Exh. 2, p. 51).
11. The physician signed a prescription and order form for the Beneficiary to continue using the TTFT device and related supplies on February 5, 2013. (Exh. 2, pp. 15-16). The physician indicated the Beneficiary was diagnosed with “glioblastoma” (ICD-9 diagnosis code 191.9). (Exh. 2, p. 1). The physician signed the order, indicating he/she believed the NovoTTF-100A System and accessories/supplies continued to be medically necessary for an additional 6-month period. *Id.*
12. The Beneficiary met with her physician on March 12, 2013. (Exh. 2, pp. 45-47). The treatment note indicated the Beneficiary was using the NovoTTF-100A System 82 percent of the time. (Exh. 2, p. 45; *see also* Exh. 2, p. 47).
13. A MRI with and without contrast was obtained on March 12, 2013. (Exh. 2, p. 48). The MRI confirmed abnormal T2 signal surrounding the postoperative cavity of the left posterior parietal region. *Id.* The changes extended into the splenium of the corpus callosum and crossed into the right lobe. *Id.* The findings were stable compared to a December 2012 study. *Id.*
14. The Beneficiary met with her physician on June 18, 2013. (Exh. 2, pp. 40-43). The treatment note indicated a MRI revealed disease progression. (Exh. 2, pp. 42, 44). The Beneficiary’s case would be discussed during the tumor board meeting to evaluate treatment options, including radiation, surgery, and/or a clinical trial. (Exh. 2, pp. 42-43).
15. The medical record includes a Letter of Medical Necessity⁷ authored by Dr. _____ on September 12, 2013. (Exh. 2, pp. 17-19). Dr. _____ was seeking to “initiate NovoTTF treatment” and requesting a predetermination of coverage and payment for the device and supplies. (Exh. 2, p. 17). Dr. _____ indicated the device was medically necessary since the Beneficiary had failed “systemic chemotherapy and all radiotherapy options approved for this clinical scenario” and was not a surgical candidate. (Exh. 2, p. 18).
16. A March 21, 2013 Invoice lists charges for the monthly rental charge of the NovoTTF-100A System. (Exh. 1, p. 2).
17. The medical record includes Invoices for May 8 and July 3, 2013 listing charges for 40 units of transducer arrays. (Exh. 2, pp. 3, 6).

⁷ The Letter of Medical Necessity contained in all 16 of the cases heard are identical but for the first and second to last paragraphs tailored to identify the beneficiary involved in the specific case, his/her diagnosis, and identifying the clinic he/she received his/her care from. *See also* Redetermination and Reconsideration requests. (Exh. 1).

18. Delivery Tickets dated May 3 and July 3, 2013 indicated the Appellant shipped 1 box of transducer arrays to the Beneficiary. (Exh. 2, pp. 9, 12).
19. A UPS Proof of Delivery indicated a package was received by the shipper on May 6, 2013 and delivered on May 8, 2013. (Exh. 2, p. 10; *see also* Exh. 2, p. 11).
20. A second UPS Proof of Delivery indicated a package was received by the shipper on July 3, 2013 and delivered on July 5, 2013. (Exh. 2, p. 13; *see also* Exh. 2, p. 14).
21. The Appellant filed a claim for the rental of the NovoTTF-100A System for 1 month (E1399-RR) with a March 21, 2013 date of service. (Exh. 2, p. 1).
22. The Appellant filed claims for 40 units of insulated transducer arrays (HCPCS code A9900-KX) with May 8 and July 3, 2013 dates of service. (Exh. 2, pp. 4-5, 7-8).
23. The hearing record does not contain an Advanced Beneficiary Notice (“ABN”) and the Appellant has waived all rights to charge and collect a fee for the service(s) at issue in this case. (Exh. 4, p. 1).
24. At hearing, Ms. Hales argued the Appellant is entitled to coverage for the NovoTTF-100A System and/or arrays since the device fell within a defined benefit category and had been established as safe and effective for the treatment of recurrent glioblastoma multiforme (“RGBM”) at the time of the date(s) of service. (Hearing CD).
25. Ms. Hales argued the NovoTTF-100A System should be found medically reasonable and necessary when considering the requirements found in chapter 13 of the *Medicare Policy Integrity Manual*. *Id.* The FDA approval, the results of the 2011 European clinical trial (“EF-11 clinical trial”), and NCCN’s guideline changes support finding the device in question was safe and effective. *Id.* The FDA’s approval, the results of the EF-11 clinical trial, and NCCN changes indicate the device was no longer investigational. *Id.* The device was an appropriate treatment option given the fact that the device was widely accepted and was being used in more than 100 oncology centers in 2013. *Id.*
26. Ms. Hales argued payment for the NovoTTF-100A System and supplies were not bundled until 2014. *Id.* The Appellant is entitled to separate payment for the device and/or supplies for services rendered in 2013. *Id.*
27. Nurse Kelly stated the effectiveness of the NovoTTF-100A System is comparable to that of chemotherapy alone. (Hearing testimony of Nurse Kelly). The device provides a patient with a better quality of life compared to chemotherapy. *Id.* There is no systemic toxicity. The most common side effect of using the device is that a patient may develop a scalp rash or irritation where the arrays are attached to his/her scalp. *Id.*

28. GBM is a rare, orphan brain cancer that affects a small portion of the population. *Id.* The initial treatment is for the patient to undergo surgical resection (when possible) followed by chemoradiation (up to dose limits) and adjuvant chemotherapy. *Id.*
29. GBM is an aggressive disease that recurs after the initial, and repeat, treatment. *Id.* A patient is diagnosed with RGBM by his/her treating physician⁸ following either a biopsy or imaging revealing the disease has returned or progressed. *Id.* Imaging, often by MRI, is more commonly used since the biopsy is a surgical procedure and most patients are not candidates for additional surgery. *Id.*
30. A patient historically is re-evaluated for further surgery, chemoradiation (up to dose limits), and chemotherapy (both initial and then maintenance). *Id.* A limited number of patients are appropriate for an additional surgery and chemoradiation treatment. *Id.* A patient typically will not survive longer than 5 months without treatment and around 12 to 14 months with treatment. *Id.*
31. The only FDA approved treatments for RGBM is the NovoTTF-100A System or possibly more Avastin⁹ (or other off-label chemo agents). *Id.* A patient's overall prognosis nevertheless remains grim. *Id.*
32. The FDA approved the Appellant's PMA application for the NovoTTF-100A System in April 2011, which is a stringent process that few devices pass. *Id.*
33. Nurse Kelly argued the TTFT treatment using the NovoTTF-100A System was a proven, established means of treating patients with RGBM prior to the date(s) of service. *Id.* The device was used in an EF-11 clinical trial involving 237 patients. *Id.* The trial revealed sufficient scientific evidence that the device was safe and as effective as chemotherapy. *Id.* The device resulted in no toxicity compared to chemotherapy. *Id.*
34. Nurse Kelly argued there was a medical consensus for the device on the date(s) of service. *Id.* The strongest literature supporting the Appellant's position is the 2012 article in the European Journal of Cancer written by Dr. Roger Stupp *et al.* *Id.* The NCCN updated the treatment guideline in late 2012 to include TTFT as an alternative treatment option for RGBM. *Id.* There were approximately 100 leading oncology centers in the United States who were certified to prescribe the device in 2013 (the number increased to hundreds more at later times). *Id.* Some private insurance companies were covering the device.¹⁰
35. Nurse Kelly explained there have been favorable developments following the date(s) of service. *Id.* A second trial evaluated the use of the Optune with Temozolomide¹¹ for

⁸ The treating physicians may include the patient's oncologist, radiation oncologist, and/or brain surgeon.

⁹ Avastin is also known by the brand name Bevacizumab. This decision will only refer to Avastin for consistency.

¹⁰ See Aetna, at http://www.aetna.com/cpb/medical/data/800_899/0827.html#dummyLink2.

¹¹ This ALJ recognizes Temozolomide is also known by the brand name Temodar. This decision will only refer to Temozolomide for consistency.

newly diagnosed GBM patients. *Id.* (see also Exh. 3). The FDA approved using the Optune with Temozolomide for newly diagnosed GBM in October 2015.¹² *Id.* The NCCN has since reclassified the use of TTFT as a Category 1 treatment option.¹³ *Id.*

36. Nurse Kelly argued the NovoTTF-100A System was reasonable and necessary for this specific Beneficiary. (Hearing testimony, individual case audio). She was diagnosed with GBM. *Id.* She underwent a resection procedure followed by chemoradiation. *Id.* She tried but could not tolerate maintenance chemotherapy. *Id.* The NovoTTF-100A System was recommended after a second recurrence. *Id.*
37. On behalf of the Contractor, Dr. Edwards argued that a supplier is not entitled to Medicare Part B coverage merely based on the fact that an item has been classified as DME. (Hearing testimony of Drs. Edwards and Hoover). The Contractor and Appellant also generally discussed or agreed that later, prospective evidence was not the basis of the Contractor's review process and entitled to less weight. *Id.*
38. There was no national or local coverage decision when this claim was initially reviewed. *Id.* The claim was therefore analyzed by the Contractor under the requirements set out in Section 13.5.1 of Chapter 13 of the *Medicare Program Integrity Manual* ("MPIM"). *Id.*
39. Dr. Edwards also argued the FDA's approved of the NovoTTF-100A System for RGBM does not entitle the Appellant to coverage. *Id.* (see also Exh. 5, p. 27; Exh. 5A, p. 12).
40. The Contractor's position is that the requirements outlined in the *MPIM* were not met. *Id.* The device did not result in meaningful improvement. *Id.* The device did not significantly prolong the patient's survival. *Id.* Any long-term side effects of using the device were unknown since the device had been used for less than 5 years. *Id.*
41. Dr. Edwards stated the costs associated with the device and supplies were not considered when determining whether the device was medically reasonable and necessary. *Id.*
42. Dr. Hoover argued the literature the Appellant cited to does not support coverage for the NovoTTF-100A System. *Id.* The conclusions reached as a result of the EF-11 clinical trial should be considered invalid. *Id.* The Appellant was involved in designing the study and recruited patients that fit the hypothesis. *Id.* The study as a whole

¹² See U.S. Department of Health & Human Services, U.S. Food & Drug Administration, at <http://wayback.archive-it.org/7993/20170111141452/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm475607.htm>.

¹³ A Category 1 designation is "based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate," indicating at least 85 percent of the panel members voted in favor of the treatment option at the time.

followed only 237 patients, some of which did not start treatment or dropped before the first cycle.¹⁴ *Id.*

43. Dr. Hoover argued the effectiveness of the NovoTTF-100A System remained questionable. *Id.* The FDA panel involved in approving the device was split. *Id.* The device was approved with the chairperson's tie-breaking vote in favor of effectiveness. *Id.* The minutes indicate there was a significant debate about how effective the device was. *Id.* The NCCN did initially categorize TTFT as a Category 2B but downgraded the status to Category 3¹⁵ in 2014. *Id.* Thereafter, the status was restored to 2B in 2015, and then remained 2B through 2018.¹⁶
44. Dr. Hoover argued the fact that an oncology center and/or physician are certified to use the device does not alone indicate general acceptance. *Id.* The certification does not mean the treatment method is being used at the center or by the physician. *Id.*

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¹⁴ Dr. Hoover did acknowledge the small size may have been related at least in part to difficulty recruiting patients who were willing to participate in the trial.

¹⁵ A Category 3 designation is "based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate," indicating there was strong disagreement among the panel members but at least 3 panel members representing 3 different institutions voted in favor treatment option at the time.

¹⁶ Some draft/discussion comments to the NCCN in 2018 suggested there is a debate between Categories 2B and 3. The adopted guidelines continue to classify TTFT as Category 2B for the treatment of RGBM and a Category 1 treatment for newly diagnosed GBM.

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (“HHS”), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (“Act”) § 1869(b)(1)(A); *see also* 42 C.F.R. § 405.1014. The Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decision of the Secretary, unless the individual/organization appeals to the Medicare Appeals Council. *Id.*

A request for hearing is timely if it is received by OMHA within 60 days after the party received the reconsideration decision, unless the individual/organization establishes good cause to extend the time to file. 42 C.F.R. §§ 405.1002(a)(1) and 405.1014(c). The Appellant is presumed to have received the QIC’s reconsideration five days after the date noted on the first page of the reconsideration, unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3).

B. Scope of Review

The ALJ considers all issues not decided entirely in the party’s favor at any prior level of review. 42 C.F.R. § 405.1032(a). The ALJ assigned to hear this matter may give notice to the parties of any other issue will be addressed at the hearing. 42 C.F.R. § 405.1032(b). The ALJ may also issue a decision on the record at the request of a party and there are no other parties who wish to appear. 42 C.F.R. § 405.1038(b). The ALJ may also issue a decision on the record on his/her own initiative if the evidence in the record supports a fully favorable finding. 42 C.F.R. § 405.1038(a).

A party may not offer new evidence for the first time at the ALJ level of review unless good cause exists. 42 C.F.R. § 405.1018(c). The party must submit a statement explaining why the evidence not previously submitted. *Id.* The ALJ will examine the statement and evidence to establish whether good cause was established. 42 C.F.R. § 405.1028(a). This restriction is not applicable to unrepresented beneficiaries or oral testimony given during the course of a hearing. 42 C.F.R. § 405.1018(d).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue and makes a decision based on the evidence, without regard to the findings made by the lower levels on the claim. 42 C.F.R. § 405.1000(d). The Appellant bears the burden of proving each element of the Medicare claim. Act §§ 1814(a)(1), 1815(b), and 1833(e); *see also* 42 C.F.R. §§ 405.1018, 405.1028, 405.1030, and 424.5(a)(6).

II. Principles of Law

A. Statutes & Regulations

The statutory authority for the Medicare program is found in Title XVIII of the Act. 42 U.S.C. § 1395 *et. seq.* The Medicare program is divided in multiple parts. Medicare Part B is a voluntary insurance program that provides medical insurance benefits to “aged and disabled individuals” for services not covered under Medicare Part A (or Part D). Act § 1831. The individual must elect to enroll in the program. *Id.* The program is financed through contributions appropriated by the Federal Government in addition to premium payments. *Id.* The Secretary of the Department of Health and Human Services has the authority to promulgate regulations which define or clarify the provisions of the Act. 42 C.F.R. § 410 *et seq.*

Section 1832 of the Act establishes the scope of benefits that are provided to an eligible beneficiary under Medicare Part B. *See also* 42 CFR §§ 410.3 and 410.10. Section 1832(a)(2)(B) of the Act indicates an individual is entitled to have payment made on his/her behalf for medical and other health services furnished by a provider of services or by others under arrangement with a provider. Section 1861(s)(6) of the Act defines the term “medical and other health services” to include durable medical equipment. *See also* 42 CFR §410.36(a)(3).

Medicare coverage for DME is determined in one of three ways. The claim must be decided consistent with an applicable “National Coverage Determination” (NCD). Act § 1869(c)(3)(B)(ii)(I). If there is no applicable NCD, the decision maker is required to consider, though is not bound, by the Local Coverage Determination (“LCD”) for the geographical area at issue. Act § 1869(c)(3)(B)(ii)(II). If there is no NCD or LCD addressing the matter, the decision maker is required to decide the matter “based on applicable information, including clinical experience and medical, technical, and scientific evidence.” Act § 1869(c)(3)(B)(ii)(III); *see also* 68 Fed. Reg. 63693.

The regulations define durable medical equipment as follows:

Equipment, furnished by a supplier or a home health agency that:

- 1) Can stand repeated use.
- 2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- 3) Is primarily and customarily used to serve a medical purpose.
- 4) Generally is not useful to an individual in the absence of an illness or injury.
- 5) Is appropriate for use in the home.

42 CFR § 414.202.

Section 1834 of the Act defines the rules for payment of durable medical equipment. *See also* 42 C.F.R. §§ 410.38(g) and 414.210.

Medicare may not make a payment under Part A or Part B for anything which is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of

a malformed body member. Act § 1862(a)(1)(A); *see also* 42 C.F.R. §§ 411.15(k) and 414.200 *et seq.* A provider or supplier is responsible for providing sufficient documentation to support the services were medically necessary, the services were provided as bill, and that payment is due. Act §§ 1833(e); *see also* 42 C.F.R. § 424.5(a)(6).

In the event the services are found to be “not medically reasonable and necessary” or “custodial in nature” under Section 1862(a)(1) or (9) of the Act, Section 1879 of the Act provides for limitation on liability for Medicare payments. The regulations address how to determine if the beneficiary or provider/supplier had the requisite degree of knowledge to make them liable under Section 1879 of the Act. 42 C.F.R. § 411.400 *et seq.*; *see also HCFA Ruling 95-1*. If a beneficiary has no knowledge that the services would not be covered, but the provider/supplier of the services did, then the provider/supplier is liable and cannot seek or retain payment made by or on behalf of a beneficiary. 42 C.F.R. § 411.404. In general, the existence of a notice, manual, or community medical standard is sufficient to constitute finding the provider/supplier had notice. 42 C.F.R. § 411.406.

B. Policy and Guidance

Unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than a NCD, can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. Act § 1871(a)(2); *see also* 42 C.F.R. § 405.1060. An NCD is the Secretary’s determination on Medicare coverage for a particular item or services applied nationally. 42 C.F.R. § 405.1060(a). An ALJ is bound by the NCD and required to ensure the NCD is applied correctly when applicable. 42 C.F.R. § 405.1060(a), (b).

The Secretary has not issued an NCD specifically addressing the DME, or the related supplies, at issue in this case. CMS, *Medicare National Coverage Determinations (Internet-Only Manual Publ’n 100-03)*, ch. 1. *See* NCD § 280.1 *et seq.* regarding DME coverage in general.

CMS and its contractors are permitted to issue policy guidance describing criteria for coverage and payment of selected items and services. 42 C.F.R. § 405.1062. This guidance is located in Medicare’s manuals and local coverage determinations (“LCD”). An ALJ is not bound by the policies outlined in a manual or LCD but is required to give the guidance substantial deference when applicable. 42 C.F.R. § 405.1062(a). An ALJ may decline to follow the guidance but must explicitly explain the reason(s) why. 42 C.F.R. § 405.1062(b). The ALJ’s decision not to follow the policy applies only to the specific claim being considered and has no precedential effect on other claims. *Id.*

CMS and CGS Administrators had not published a LCD addressing the DME and related supplies as of the date(s) of service at issue.¹⁷

¹⁷ The Contractor did not draft an LCD addressing the NovoTTF-100A System and publish it for comments until after the date(s) of service.

The *MPIM* indicates the Contractor is required to make individual claim determinations in the absence of an NCD and LCD. *MPIM (Internet-Only Manual Publ'n 100-08)*, ch. 13 § 13.3 (Jan. 2013). The decision is to be based on the medical reviewer's clinical judgement in light of the reasonable and necessary provisions outlined in Section 13.5.1. *Id.*

Reasonable and Necessary

Contractors shall describe in the draft LCD the circumstances under which the item or service is reasonable and necessary under 1862(a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
 - o Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
 - o Furnished in a setting appropriate to the patient's medical needs and condition;
 - o Ordered and furnished by qualified personnel;
 - o One that meets, but does not exceed, the patient's medical need; and
 - o At least as beneficial as an existing and available medically appropriate alternative.

There are several exceptions to the requirement that an item or service be reasonable and necessary for diagnosis or treatment of illness or injury. The exceptions appear in the full text of § 1862(a)(1).

MPIM, ch. 13 § 13.5.1; *see also Almy v. Sebelius*, 679 F.3d 297, 299 (4th Cir. 2012).

The Contractor is required to use the "strong evidence available." *MPIM*, ch. 13 § 13.7.1.

In order of preference, LCDs should be based on:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
- General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
 - o Scientific data or research studies published in peer-reviewed medical journals;
 - o Consensus of expert medical opinion (i.e., recognized authorities in the field); or
 - o Medical opinion derived from consultations with medical associations or other health care experts.

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general

acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

Id.

The *Medicare Benefits Policy Manual* (“MBPM”) defines reasonableness and necessity with regard to DME specifically. *MBPM (Internet-Only Manual Publ’n 100-2)*, ch. 15, § 110 (Oct. 2003). An item classified as DME will not be covered in every instance.” *MBPM*, ch. 15, § 110.1.C. The item(s) must be “necessary and reasonable for treatment of an illness or injury, or to improve the functioning of a malformed body member.” *Id.* The *MBPM* states:

1 - Necessity for the Equipment

Equipment is necessary when it can be expected to make a meaningful contribution to the treatment of the patient's illness or injury or to the improvement of his or her malformed body member. In most cases the physician's prescription for the equipment and other medical information available to the DMERC will be sufficient to establish that the equipment serves this purpose.

2 - Reasonableness of the Equipment

Even though an item of DME may serve a useful medical purpose, the DMERC or intermediary must also consider to what extent, if any, it would be reasonable for the Medicare program to pay for the item prescribed. The following considerations should enter into the determination of reasonableness:

1. Would the expense of the item to the program be clearly disproportionate to the therapeutic benefits which could ordinarily be derived from use of the equipment?
2. Is the item substantially more costly than a medically appropriate and realistically feasible alternative pattern of care?
3. Does the item serve essentially the same purpose as equipment already available to the beneficiary?

3 - Payment Consistent With What is Necessary and Reasonable

Where a claim is filed for equipment containing features of an aesthetic nature or features of a medical nature which are not required by the patient's condition or where there exists a reasonably feasible and medically appropriate alternative pattern of care which is less costly than the equipment furnished, the amount payable is based on the rate for the equipment or alternative treatment which meets the patient's medical needs.

The acceptance of an assignment binds the supplier-assignee to accept the payment for the medically required equipment or service as the full charge and the supplier-assignee cannot charge the beneficiary the differential attributable to the equipment actually furnished.

Id.

The *MPIM* identifies what documentation a supplier is required to retain for at least a 7-year period. *MPIM*, ch. 5. The supplier is required to have an order from the physician prior to delivering the DME and/or related supplies. 42 C.F.R. § 410.38; *MPIM*, ch. 5, §§ 5.2.1, 5.2.2, and 5.2.3. The supplier must obtain a detailed written prior to filing a claim. *Id.* The supplier is required to maintain proof of delivery. *MPIM*, ch. 4, § 4.26.1 and ch. 5, § 5.8.

All Medical records must be authenticated by the author. *MPIM*, ch. 3, § 3.3.2.4. The method used shall be a handwritten or electronic signature, as stamped signatures are not acceptable. *Id.*

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ANALYSIS

A. INTRODUCTION AND ISSUES

This ALJ with jurisdiction conducted a *de novo* review of the evidence to first determine if the NovoTTF-100A System¹⁸ is medically reasonable and necessary in general for the treatment of recurrent GBM (“RGBM”).¹⁹ The dates of service in this case, and all the related cases held during the consolidated hearing, involve the 2013 calendar year. Thus, this general determination turns on whether the NovoTTF-100A System was merely investigational and experimental in 2013 or if it had been proven safe and effective, was widely accepted by the medical community, and appropriate for the treatment of RGBM in 2013. This general topic shall be referred to as the “Investigational and Experimental Issue,” as it was at the prehearing conference and during the hearing, and is located in Section C.²⁰

Second, for each specific patient in this series of cases, this ALJ reviewed the specific medical reasonableness and necessity of the treatment for the Novo-TTF-100A System in Section D.

Third, some cases in the hearing group also involved additional case-specific issues, such as whether there was manufacturer pricing information in the record, whether the arrays were separately payable and coded in 2013, or whether there was proof of delivery. These specific issues will be identified and resolved on a case by case basis in Section F. In this particular case, the additional issues raised relate to the manufacturer pricing information. (Exh. 1, pp. 1-7).²¹

Lastly, the discussion of any liability allocation can be found in Section F.

B. SUMMARY OF RESULT IN THIS SPECIFIC CASE

This ALJ has determined that the NovoTTF-100A System, and related transducer arrays, was more than investigational and experimental, and generally an acceptable form of last resort medical treatment for RGBM in 2013 for appropriate patients. The DME status of the device at issue is not contested. The medical record contains a physician’s order for the device and supplies, adequate proof of manufacturer pricing, and proof of delivery. The Appellant thus prevails on the threshold issues. However, in this specific matter, this ALJ was FAVORABLE on the specific merits of coverage. The NovoTTF-100A System and insulated transducer arrays were medically reasonable and necessary as applied to this Beneficiary.

¹⁸ The NovoTTF-100A System is a piece of durable medical equipment and the insulated transducer arrays are a required supplies for the system. The device is now known under the name, Optune® TTFT.

¹⁹ The term ‘progressive’ is used interchangeably with ‘recurrent’.

²⁰ As an aside, there is no question, and acceptance by CMS that the device is at least Durable Medical Equipment (DME) so that is discussed only briefly in Section C. Similarly, no NCD or LCD directly on point existed during the dates of service, and so discussion of the same is minimal and reference to sub-regulatory guidance is primary to applicable CMS Manuals.

²¹ For efficiency, this ALJ will present the QIC and Contractor’s additional reasons for denying the claim harmoniously in a joint presentation.

C. GENERAL NECESSITY – WAS THE NOVOTTF-100A SYSTEM ‘INVESTIGATIONAL AND EXPERIMENTAL’ FOR THE TREATMENT OF RGBM IN 2013?

NovoTTF-100A System meets the definition of DME (But Analysis Must Continue)

In general, for an item of DME to be covered by Medicare, it must be eligible for a defined Medicare benefit category, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and meet all other applicable statutory and regulatory requirements. Act § 1862(a)(1)(A). The documentation must demonstrate the DME, and supplies, satisfy the medical reasonable and necessary standard. *MPIM*, ch. 5, § 5.7. The *MPIM* states the medical records should include information about a patient’s diagnosis and other pertinent information to substantiate medical necessity for the type and quantity of items ordered as well as the frequency of use and replacement. *MPIM*, ch. 5, §§ 5.7 and 5.8.

A supplier is required to maintain a record of the dispensing order, the detailed written order, Certificate of Medical Necessity or DME Information Form (if applicable), and proof of delivery in addition to information related to a beneficiary’s diagnosis. *MPIM*, ch. 5, § 5.8; *see also MPIM*, ch. 5, §§ 5.2 and 5.3. If the information in the patient’s medical record does not adequately support the medical necessity for the item, or there is missing documentation, the supplier is liable for the cost of the item absent a valid Advance Beneficiary Notice. *MPIM*, ch. 5, §§ 5.7 and 5.8; *see also* Act § 1833(e) and 42 C.F.R. § 424.5(a)(6).

It is uncontested that the NovoTTF-110A System is DME that falls within a defined benefit category. (Exh. 1, p. 35). CMS issued an interpretation or bulletin to this effect in July 2013.²² However, as the Contractors (and Appellant) correctly pointed out, the mere status that the NovoTTF-100A System was accepted as a piece of DME is not the primary inquiry in this case, and insufficient alone to achieve coverage.

General Medical Necessity

Evaluating Medical Necessity in General

In this case, there was no formal guidance in the form of an NCD or LCD addressing the DME (and supplies) at issue on the date(s) of service. Section 522 of the Benefits Improvement and Protection Act permits a contractor to issue a decision addressing whether and in what circumstances an item or service is covered as reasonable and necessary under Section 1862(a)(1)(A) of the Act. *MPIM*, ch. 13, §§ 13.1.3 and 13.5.1. The *MPIM* indicates the contractor “shall consider a services to be reasonable and necessary if the contractor determines that the services is:” (1) safe and effective; (2) not experimental or investigational; and (3) appropriate. *Id.* The contractor is to consider all applicable information when making a

²² See NCD 280.1 generally.

determination on a claim in those cases where there is no applicable NCD or LCD. Act § 1869(c)(3)(B)(i)(III).²³

TTFT Treatment is Safe, Effective, and Not Investigational or Experimental

This ALJ considered the hearing record and finds the Appellant's arguments with the witness testimony and publications indicate using the NovoTTF-100A System to treat RGBM was medically reasonable and necessary in 2013 since the device was safe, as effective the chemotherapy alternative, and not investigational/experimental.

The Appellant's argument and witness testimony meanwhile focused on the initial PMA showing that the NovoTTF-110A System was proven at least as good as continued/repeat chemotherapy with Avastin or other agents. The NovoTTF-100A System resulted in a substantially better quality of life given the device resulted in fewer adverse side effects. For example, the NovoTTF-110A System usually only presents a skin rash as a typical side effect compared to the well-known systemic damage chemotherapy can cause.²⁴

This ALJ independently reviewed the articles the Appellant provided and finds they support the Appellant's position that the NovoTTF-100A System is safe and effective for the treatment of RGBM. (Exh. 3). The Appellant provided this ALJ with various articles initially documenting changes observed in the cell structure, animal trials followed by a Phase I human trial with the NovoTTF-100A. (Exh. 3). The initial human clinical trial was comprised of 10 individuals diagnosed with RGBM and was successful for its purpose.²⁵

Thereafter, and more central to this case, the significantly larger EF-11 clinical trial was then held prior to the dates of service. The clinical results were published in the *European Journal of Cancer* in 2012. (Exhs. 1-3, and Hearing CD).²⁶ The EF-11 clinical trial initially comprised with 237 patients with RGBM was concluded in 2011.²⁷ Of the 237 patients, 120 patients from 28 institutions over 7 countries were scheduled to receive TTFT treatment. Ninety-three of these patients completed at least 1 cycle, or 4 weeks of TTFT treatment. The remaining 117 patients were scheduled to receive chemotherapy treatment, and all but one patient completed one cycle.

²³ NCD, ch. 1, § 280 *et seq.*, governs DME in general. There are no provisions addressing TTFT.

²⁴ Familiarity with the detailed, multi-hour general hearings are assumed, and cited *passim*. This is a mere paraphrase and not intended as a complete list of the parties/participant's respective testimony. See Findings of Facts for more details. The hearing arguments and testimony also included substantial discussions about the nature of the PMA process, the PMA vote and subsequent events. These statements were considered and are discussed below.

²⁵ See articles, *Disruption of Cancer Cell Replication by Alternating Electric Fields*, *Alternating electric fields arrest cell proliferation in animal tumor models and human brain tumors*, and *TTFields alone and in combination with chemotherapeutic agents effectively reduce the viability of MDR cell sub-lines that over-express ABC transporters*. A clinical trial involved 20 individuals, 10 of which were diagnosed with RGBM patients. See also articles, *Chemotherapeutic treatment efficacy and sensitivity are increased by adjuvant alternating electric fields*; *Tumor treating fields: concept, evidence and future*; and *NovoTTF-100A: a new treatment modality for recurrent glioblastoma*.

²⁶ See article, *NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma; a randomised phase III trial of a novel treatment modality*, *Eur. J. Cancer* (2012) 48, 2192-2202, Roger Stupp, *et al.*

²⁷ One article does indicate 8 percent of the patients reportedly had a history of a lower grade glioma prior to being diagnosed with RGBM.

The overall survival rate of patients treated with TTFT was not superior but was comparable to the overall survival rate of patients treated with chemotherapy. Similarly, the FDA's pre-market approval of TTFT for RGBM in April 2011 was based on the FDA's conclusion, in its Summary of Safety and Effectiveness Data document, that "NovoTTF-100A treatment exhibits minimal toxicity, clinically comparable primary and secondary effectiveness and better quality of life compared to the chemotherapies in the control arm of the study."²⁸

Moving on to the hard data, the EF-11 clinical trial indicated 20 percent of patients from each treatment group were alive after 1 year. The results dropped to eight percent of TTFT patients alive at the end of two years in contrast to five percent of patients treated with chemotherapy. The results fell to four percent and one percent at the end of year three respectively.²⁹

Thus, this ALJ finds the studies collectively indicate TTFT treatment was safe and at least as effective as chemotherapy to treat RGBM. The most common side effect of the TTFT was scalp dermatitis, a relatively minor side effect which could be addressed with steroids and adjusting the placement of the arrays. Another theoretical side effect of the TTFT could be a neurological disorder, but this did not feature in the record(s) or unduly concern the FDA, and most neurological deterioration would be logically related to the underlying RGBM.

The medical community's acceptance of the NovoTTF-100A System as a means of treating RGBM supports the Appellant's argument that the device was safe and effective in 2013. The FDA approved the Appellant's PMA in April 2011 for RGBM. This ALJ recognizes the panel of 12 physicians were split 6-6 on whether the device was effective.³⁰ The chairperson's vote resulted in the panels' ultimate recommendation. The FDA presumably at least in part relied on the recommendation when it approved the PMA. To date, the FDA has never withdrew the approval, or issued any warnings.

The NCCN did not immediately add TTFT treatment to its guidelines in 2011. The guidelines were changed to add TTFT as a treatment option in late 2012, or more than a year after the FDA's approval. This ALJ finds the Appellant has established by a preponderance of the evidence indicates the NovoTTF-100A System was safe and effective for the treatment of RGBM.

This ALJ considered the testimony offered by the Contractor. The focus of Drs. Edwards and Hoover's testimony was on the effectiveness of the NovoTTF-100A System. The Contractor raised multiple concerns about how the EF-11 study (and the initial study) was conducted. In part, the Contractor was concerned about the size of the clinical trials leading up to the 2011 PMA for the NovoTTF-110A System. The Contractor thought the *n* value, or number of participants, of the study arms were relatively small. The EF-11 clinical trial was only comprised

²⁸ FDA PMA P100348, p. 38 (April 8, 2011).

²⁹ This ALJ did not focus on any mortality difference because the Appellant did not argue this point. The mean survival rate was possibly higher in those patients treated with TTFT as opposed to chemotherapy with respect to those RGBM patients in whom Avastin failed (which was not the direct focus of the EF11 study).

³⁰ The panel voted unanimously that the device was safe. The panel ultimately recommended the NovoTTF-100A with a 7-3 vote (two members abstained from voting).

of 237 total participants, of which 120 of those participants were scheduled to receive TTFT monotherapy. Only 93 of the original 120 participants started and completed 4 weeks of treatment, or one cycle. Additionally, the Contractor was also concerned about the manufacturer's involvement in the EF-11 clinical trial.³¹ The Contractor acknowledged there were some relative benefits to treating a patient with TTFT, such as quality of life and slightly slower mortality rate, but suggested this did not demonstrate the NovoTTF-100A System was actually effective.

The Contractor's witnesses raised reasonable and thoughtful points, but this ALJ thinks the Appellant's case (and burden of proof) is strong enough, e.g. a civil preponderance of the evidence, to rebut or survive those concerns. In part, this ALJ does not agree with the Contractors' argument that the results should be considered invalid merely because the EF-11 clinical trial consisted of only 237 patients split into 2 arms. GBM is an aggressive, fatal orphan disease that only affects a small fraction of the population. About 10,000 individuals are diagnosed with GBM each year. An "n" value greater than 30, and even 60 and 90, appears sufficient to provide statistical evidence that using the NovoTTF-100A system was non-inferior to chemotherapy.³² Furthermore, 93 patients in the TTFT arm that completed at least one cycle represented a little more than 2.5 percent of individuals diagnosed with GBM each year. The population used was significant given the aggressive nature of the disease and high mortality rate.

In addition, the fact that physicians associated with the Appellant were involved in the EF-11 clinical trial does not negate or diminish the ultimate findings. The hearing record suggests the NovoTTF-100A System was the only TTFT device being developed at the time. It is reasonable the Appellant would maintain some degree of involvement in the EF-11 clinical trial (and subsequent trials) to ensure the device was being used properly to achieve the most accurate results, and because of the linked practical reality of needing manufacturer/developer involvement when testing a piece of DME.

Finally, the fact that the EF-11 clinical trial was converted from a superiority study to non-inferiority study with no palliative arm does not suggest the results should be considered unreliable. The decision to change was sufficient since it afforded the participants greater safety and comfort. Entitled to heavy weight as well, is that the FDA, through the PMA process, actually directed the Appellant to change to a non-inferiority study for the best interests of the patients. The use of a palliative arm would also have been impractical and ethically challenging given the diagnosis. It would likely have been difficult to recruit a large number of RGBM patients willing to only accept hospice care.

³¹ See Exh. 3. This ALJ reviewed each of these articles in detail. One author in each article was directly connected to the Appellant.

³² This ALJ finds the size of the sample reasonable since GBM is an orphan disease. This ALJ agrees with the Appellant's argument that it would be unreasonable to require a larger study typical for common diagnoses involving millions of potential patients, such as in cardiac disease and related intervention procedures, stroke, diabetes mellitus and chronic obstructive pulmonary disease.

This ALJ recognizes the Appellant and Contractor are in agreement that the NovoTTF-100A System does provide a patient with a higher quality of life (“QOL”) and fewer side effects compared to chemotherapy. A patient’s pursuit for medical-related QOL is a meritorious clinical goal, and a highly individual choice. This result dovetails with this ALJ’s ultimate determination that the NovoTTF-100A System is non-inferior to chemotherapy while offering a substantially higher QOL. The device is covered as a last resort treatment option for appropriate individuals diagnosed with RGBM for whom the device meets the statutory structure of reasonable and necessary as outlined under Medicare Part B.

In summary, multiple clinical trials evaluating the effects of the NovoTTF-100A System on patients with RGBM had concluded by 2011. The FDA approved the Appellant’s PMA to use the NovoTTF-100A System to treat patients with RGBM. This ALJ finds the hearing record demonstrates as a whole that the NovoTTF-100A System was no longer experimental or investigational for treating RGBM.

However, discussed in more detail below, this ALJ rejects expanding or limiting coverage based on events that occurred after 2013. One of the Appellant’s arguments is that the NovoTTF-100A System is appropriate for *other* diagnosis. The FDA, and NCCN, has since expanded the use of the Optune as part of the frontline treatment after a patient is initially diagnosed with GBM. Some of the Appellant’s claims indicate the NovoTTF-100A System was prescribed to treat other central nervous system cancers. The Appellant has not provided evidence the medical community supported a broader use for these additional diagnoses in 2013. Similarly, this ALJ has not disallowed coverage based on the LCD published after the date(s) of service.

Appropriateness & Sufficient Medical Community Acceptance

The hearing record as a whole demonstrates the NovoTTF-100A System was an appropriate treatment option for RGBM on the date(s) of service. This ALJ specifically focused on three of the listed areas: furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of RGBM, whether the device was just as effective as the best practices standard, and how frequent the device was used during a given period. *MPIM*, ch. 13, § 13.5.1.

First, the hearing record does demonstrate the accepted standard of medical practice for the treatment of RGBM in 2013 included the NovoTTF-100A System. The Appellant argued the 12-person panel convened by the FDA unanimously voted the device was safe and half of the panel was persuaded that the device was effective. (Hearing testimony). The FDA considered the panel’s recommendation when it approved the Appellant’s PMA. *Id.* The NCCN amended the guidelines for the treatment of RGBM in late 2012 to include TTFT. *Id.* Commercial insurance companies were starting to cover the device for RGBM. *Id.* As of 2013, about 100 oncology centers were certified to prescribe the device. *Id.*

Drs. Edwards and Hoover collectively argued the NovoTTF-100A System was not the accepted standard of medical practice. The FDA’s approval of the device does not mean the device is covered under Medicare. *Id.* One cannot conclude that because a center is certified that the physicians associated with that center are prescribing the device. *Id.* The NCCN subsequently downgraded the category to Category 3 in 2014 (before raising it back to 2B in 2015). *Id.* The

Contractor located no published policies that indicated a commercial insurance provider was covering the device when it initially evaluated the claim. *Id.*

This ALJ is moved by the fact that the FDA approved the Appellant's PMA application in 2011, and had been in effect for nearly two years before the date(s) of service. This ALJ is further moved by the fact that the NCCN changed its guidelines. The Category 2B status in effect during the date(s) of service indicates that no less than half the NCCN panel members were persuaded the NovoTTF-100A System was a treatment option for RGBM. The NCCN cited to the FDA approval and EF-11 clinical trial. "Similar survival was observed in the arms, and TTF therapy was associated with lower toxicity and improved quality of life." The NCCN's recommendation in 2013 for RGBM reads:

Patients should be followed closely with serial MRI scans (at 2-6 weeks post-RT, then every 2-4 months for 2-3 years, then less frequently) after the completion of RT. Because RT can produce additional BBB dysfunction, corticosteroid requirements may actually increase therefore, scan may appear worse during the first 3 months after completion of RT, even though no actual tumor progression is present. Early MRI scans allow for appropriate titration of corticosteroid doses, depending on the extent of mass effect and brain edema. Later scans are used to identify tumor recurrence. Early detection of recurrence is warranted, because local and systemic treatment options are available for patients with recurrent disease. However MR spectroscopy, MR perfusion, or PET can be considered to rule out radiation-induced necrosis or "pseudoprogression."

Management of recurrent tumors depends on the extent of disease and patient condition. For local recurrence, repeat resection, with or without wafer placement in the surgical bed, can be performed if possible. After reresection, or if the local recurrence is unresectable, patients with poor PS should undergo palliative/best supportive care without further active treatment. If PS is favorable, systemic chemotherapy may be administered (especially for anaplastic oligodendroliomas); reirradiation is a category 2B option to consider if prior radiation procedures a good/durable response. Patients with recurrent glioblastoma may also consider alternating electric field therapy (category 2B). In the case of diffuse or multiple recurring lesions, the options are: 1) palliative/best supportive care for patients with poor POS; 2) systemic chemotherapy; 3) surgery to relieve mass effect; or 4) consider alternating electric field therapy for glioblastomas (category 2B).

All patients should receive best supportive care.

Furthermore, some commercial insurance companies were starting to cover the NovoTTF-100A System for RGBM as of the date(s) of service. Aetna began covering the device on March 19, 2013. Humana started covering the device the following a month. This ALJ finds the Appellant has persuasively demonstrated by a preponderance of the evidence that the NovoTTF-100A System had been accepted by the medical community as a treatment option for RGBM.

Secondly, the hearing record demonstrates the NovoTTF-100A System was at least as effective as the best practices standard, or chemotherapy. The Appellant argued the results of clinical studies revealed the NovoTTF-100A System was as effective as chemotherapy. (Hearing argument/testimony). The device resulted in less physical adverse symptoms compared to chemotherapy. *Id.*

This ALJ considered the arguments and testimony with the language of the *MPIM*. The effectiveness of the NovoTTF-100A System being as good as chemotherapy with less severe side effects is “meaningful improvement” within the meaning of the *MPIM*. Additionally, this ALJ does not read the *MPIM* to require TTFT result in a meaningful improvement beyond established treatment options that are already covered by Medicare. *MPIM*, ch. 13, § 13.5.1. The language clearly states “at least as beneficial” as existing treatment options is sufficient, a standard which is met. *Id.* The Appellant has presented evidence that the EF-11 clinical trial revealed individuals treated with the NovoTTF-100A System had the same overall survival rate at the end of year 1 as those treated with chemotherapy. The overall survival rate at the end of years 2 and 3 was higher for those patients treated with the NovoTTF-100A System compared to chemotherapy.

This ALJ finds the Appellant has demonstrated by a preponderance of the evidence that the NovoTTF-100A System is at the very least as effective as chemotherapy to treat RGBM, safe and with less side effects, and satisfies the *MPIM* as a treatment option for RGBM (when medically necessary for the specific patient).

Additionally, this ALJ considered the appropriate frequency for the NovoTTF-100A System with regard a patient’s compliance. This issue was not specifically addressed during the global argument/testimony. (Hearing testimony). Ms. Hales’ statements and Nurse Kelly’s testimony addressed each of the Beneficiaries’ compliance when summarizing the specifics of each case. (Hearing testimony, individual case audio). The articles indicate the clinical trials involved the participants using the NovoTTF-100A System 18 hours a day on average. (Exh. 3). The Appellant’s Product Dossier clearly indicates “the recommended average daily use is at least 18 hours.” *Id.* This ALJ finds the NovoTTF-100A System is appropriate for daily use, with the expectation that a patient will use it 18 hours a day on average, or roughly 75 percent of the time.

Changes Following the Date(s) of Service Considered but Given Much Less Weight

There have been significant changes related to the NovoTTF-100A System since 2013. CMS assigned the NovoTTF-100A System a payment classification designation effective on January 1, 2014. The Appellant had billed the NovoTTF-100A System under miscellaneous HCPCS code E1399 and the insulated transducer arrays under miscellaneous supply HCPCS codes A9900 and A9999. CMS assigned HCPCS codes E0766 and A4555 to the device and arrays respectively. Payment for both the device and arrays would be bundled under E0766.

The FDA expanded its approval of the Optune, the second generation of the NovoTTF-100A System. The Appellant filed a supplement PMA application on April 10, 2015. The FDA approved the PMA on October 5, 2015. The FDA’s approval permitted using the Optune with Temozolomide “for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy.”

The NCCN has updated the guidelines related to RGBM on multiple occasions. The category was initially downgraded in 2014 to a “3,” indicating there was major disagreement that the

intervention was appropriate.³³ The use of TTFT was upgraded back to Category 2B around April 2015. The use of TTFT remains at a Category 2B for RGBM while the treatment option is a Category 1 for newly diagnosed GBM.

A number of JAMA articles³⁴ in 2015, 2017 and 2018, in part reporting on the EF-14 study, have also emerged that support in randomized clinical trials, that TTFT (plus Temozolomide) is preferable to Temozolomide alone as a therapy for newly diagnosed glioblastoma. However, this ALJ does not think the JAMA articles change the central analysis or result in this case given the RGBM context.

Meanwhile, the Contractors collectively issued a local coverage determination, *LCD L34823*, in October 2015. *Local Coverage Determination L34823: Tumor Treatment Field Therapy (LCD L34823)*. The LCD indicates that tumor treatment field therapy “will be denied as not reasonable and necessary.” *Id.* The LCD includes no discussion of the analysis outlined in the *MPIM*. *Id.* The comments and responses suggest the decision not to cover the DME was because: 1) the FDA panel was evenly split on the question of efficacy with the chairperson’s vote breaking the tie; 2) the NCCN’s categorization of 2B indicated there was a consensus but the consensus was not uniform; and 3) the Compendia’s failure to include a narrative discussing the 2B category indicates those items do not fit Medicare’s definition of “generally medically accepted” category. *Id.*

This ALJ duly considered the changes that occurred after the date(s) of service but afforded the information little weight. This ALJ recognizes the FDA did broaden the PMA to use TTFT for individuals newly diagnosed with GBM, which is not at issue in the cases before this ALJ. The Contractor issued the initial version of the LCD days before the October 2015 approval. The LCD has been revised but continues to deny coverage for TTFT without discussing why the device is not medically reasonable and necessary in any circumstance while commercial insurance companies permit coverage in certain circumstances. Notably, this ALJ reviewed the sources the Contractors considered and found the FDA’s 2015 approval of the Appellant’s supplemental PMA was not considered. The Contractor has not cited to more recent publications.

Nevertheless, these events occurred following the date(s) of service and this ALJ finds it would be inappropriate to decide these cases prospectively. This ALJ focused on the information available on the date(s) of service when determining the use of the NovoTTF-100A System was medically reasonable and necessary for appropriate patients (addressed previously).

Specific Requirements Needed to Demonstrate Medical Necessity

This ALJ considered the Appellant’s arguments, the literature the Appellant provided, and the witnesses’ testimony when establishing the specific requirements for coverage of the NovoTTF-100A System and/or insulated transducer arrays. This ALJ has taken judicial notice of information published by the federal agencies and the NCCN.

³³ The change may reflect the consensus of those on the panel at the time.

³⁴ The Journal of the American Medical Association.

The Appellant's burden is to prove by a preponderance of the evidence that the documentation submitted with the claim(s) satisfies six requirements. The Appellant's basic argument is that Medicare should cover the NovoTTF-100A System since the FDA approved the device prior to the date of service. This ALJ agrees in general with the Appellant's argument and finds coverage for the NovoTTF-100A System is medically necessary if the factors identified in the April 2011 PMA are present. Moreover, this result is consistent with the information in the Product Dossier and the NCCN guidelines in effect in 2013. (Exh. 3; Exh. 6). However, to the degree, if any, that the Appellant might contend this case (involving older dates of service and before subsequent broadening modifications to the FDA approval or NCCN guidelines) would allow an approval broader than the April 2011 PMA, this ALJ does not reach that far for these dates of service. The April 2011 PMA approval states in pertinent part:

This device is indicated for treatment of adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme, following histologically- or radiologically confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GB after surgical and radiation options have been exhausted.

(Exh. 1, p. 38).

This ALJ finds the approval itself appears to contain five separate requirements. The requirements are as follows:

- 1) the individual must be at least 22 years old;
- 2) the individual's medical history includes a diagnosis of GBM;
- 3) there is histological or radiological evidence of RGBM in the supratentorial region of the brain after the individual received chemotherapy;
- 4) the individual is not a candidate for further surgery or radiation; and
- 5) the TTFT is being used as a monotherapy.

These requirements are also consistent with the information in the Product Dossier and the NCCN guidelines in effect in 2013. (Exh. 3; Exh. 6).

With regard to the third (and any other impacted elements), this ALJ has required the medical record contain proof of histological or radiological evidence of RGBM in the supratentorial region of the brain after an individual has received chemotherapy. However, this ALJ has permitted some flexibility with regard to how this proof is documented. This ALJ will not require the medical record contain the actual imaging report that revealed recurrence in the supratentorial region of a patient's brain following chemotherapy. The Appellant only needs to provide a treatment note, progress note, or supplemental statement in the medical record (a supplier statement alone is insufficient) that addresses the findings.

This ALJ recognizes there might be instances where the medical record indicates a patient received Avastin (or a similar chemotherapy) while he/she was prescribed and using the NovoTTF-100A System. Avastin is the only other FDA approved treatment for RGBM. It is reasonable a physician may recommend and a patient elects to complete his/her then-current

cycle of chemotherapy while he/she begins using the NovoTTF-100A System. This ALJ recognizes, as outlined in the April 2011 FDA PMA, the device is intended to be a monotherapy to treat RGBM. This ALJ will permit coverage for the device in those instances where the chemotherapy was started prior to a physician's order for the device and the chemotherapy is stopped at the end of the. Coverage will be denied if the medical record suggests the two are being used a polytherapy, i.e. an additional cycle is started or chemotherapy is added to a patient's treatment regimen at the same time or after the physician ordered the device.

The sixth and final requirement is compliance. The Appellant's Product Dossier and the articles indicate the ideal treatment is for a patient to use the NovoTTF-100A System 18 hours a day on average. (Exh. 3). This ALJ has relied on this information when finding the medical record should demonstrate a patient used the device about 75 percent of the time prior to and/or during the dates of service. The medical record must specifically address a patient's compliance prior to and/or during the dates of service but some oral testimony may be used to explain or round out the data. However, oral testimony alone is insufficient because it does not comply with the *MPIM*. *MPIM*, ch. 5, §§ 5.7 and 5.8. Additionally, this ALJ recognizes there were instances where a patient's compliance was slightly less than 75 percent, but fluctuated. This ALJ reviewed the medical record and considered the oral testimony on a case-by-case basis.

D. SPECIFIC MEDICAL NECESSITY IN THIS CASE

The medical record establishes all six requirements are present in this specific case, and therefore the Appellant is entitled to coverage in this specific case.

The first requirement is met. This Beneficiary was 65 years old on the date(s) of service.

The second requirement is met. The medical record does not include a copy of the May 2011 pathology report. (Exh. 2). The treatment notes however do indicate a pathologist did examine a piece of the resected tissue and confirmed a diagnosis of GBM. (Exh. 2, p. 49).

The third requirement is met. The medical record as a whole suggests this Beneficiary's past treatment regimen included a chemotherapy agent. (Exh. 2). The March 2013 MRI confirmed the enhancement extended into the splenium of the corpus callosum and had crossed into the right lobe. (Exh. 2, p. 48). The changes were described as consistent with the recurrence/progression of the initial tumor.

The fourth requirement is met. This ALJ relied on the physician's attestation in the Letter of Medical Necessity that this Beneficiary was not a candidate for additional surgery. (Exh. 2, p. 18). Radiotherapy was considered but determined not to be a viable treatment option at the time. *Id.* The statement is consistent with the MRI findings that the enhancements involved multiple aspects of the supratentorial region of the brain. (Exh. 2, p. 48).

The fifth requirement is met. The medical record does indicate this Beneficiary was considering Avastin and the NovoTTF-100A System in September 2012. (Exh. 6, p. 1). This ALJ reviewed the medical record closely and did not locate a statement indicating a physician did prescribe Avastin and this Beneficiary used it concurrently while also using the NovoTTF-100A System.

(Exh. 2). It is reasonable this medication was not prescribed since she had previously tried a maintenance dose of Temozolomide and was unable to tolerate the chemotherapy agent. The medical record indicates the NovoTTF-100A System was prescribed and this Beneficiary used it as a monotherapy to treat the RGBM.

The sixth and final requirement is met. The March 12, 2012 treatment note indicated this Beneficiary's compliance was 82 percent, well above the required 75 percent. (Exh. 2, p. 45). This ALJ recognizes this Beneficiary's compliance was not subsequently addressed in the medical records. The medical also does not document this Beneficiary voiced any complaints regarding the NovoTTF-100A System, such as skin lesions. It is reasonable to assume her compliance remained at or near 82 percent throughout the dates of service at issue. This ALJ finds the Appellant has established by a preponderance of the evidence that the coverage requirements for the NovoTTF-100A System were met.

Because the Appellant is entitled to coverage for the NovoTTF-100A System, the Appellant is also entitled to coverage for the accessories and/or supplies related to the NovoTTF-100A System. This ALJ finds the insulated transducer arrays are covered.

For the reasons indicated above, this ALJ finds the NovoTTF-100A System was medically reasonable and necessary for this Beneficiary on the date(s) of service. The insulated transducer arrays were also medically reasonable and necessary. The Appellant is entitled to coverage and reimbursement for these services under Medicare Part B.

E. OTHER ISSUES RELATED TO PAYMENT AND/OR DOCUMENTATION

The Appellant has provided evidence of the manufacturer's suggested price for the NovoTTF-100A System and the insulated transducer arrays. The record includes copies of the Invoices. (Exh. 2, pp. 2-3, 6). The Invoice identifies the rental price for one (1) month of renting the NovoTTF-100A System as \$5,500. *Id.* The unit price for the purchase of one (1) transducer array is \$350, and a month's supply of 40 units is \$14,000. *Id.* This ALJ finds the Appellant has provided Medicare with the manufacturer's suggested retail price for the item(s) at issue.

The Appellant prevailed on this additional issue, and on coverage in general (see previous Sections). The Contractor is required to consider the manufacturer's suggested pricing information provided when determining the amount of reimbursement the Appellant is entitled to.

F. LIMITATION OF LIABILITY

There is no issue regarding liability since the services at issue were medically reasonable and necessary.

Conclusions of Law

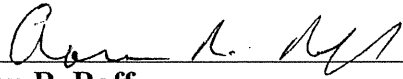
This decision is **FULLY FAVORABLE** for the Appellant. The monthly rental charges for the NovoTTF-100A and/or 40 units of insulated transducer arrays (HCPCS code A9900) the Appellant billed on March 21, 2013, May 8, 2013, and July 3, 2013 were medically reasonable and necessary. The Appellant is entitled to Medicare Part B coverage and payment for the DME and supplies on the respective dates of service.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated: JUN 21 2018



Aaron R. Raff
U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, Missouri

Appeal of: **Novocure, Inc.**

ALJ Appeal No.: **1-2665644382**

Beneficiary:

Medicare: **Part B**

HICN:

Before: **Aaron R. Raff**
U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented, this Administrative Law Judge (“ALJ”) enters a **FULLY FAVORABLE** decision for the Appellant, Novocure (“Appellant”). At issue is a claim involving 40 units of insulated transducer arrays (HCPCS code A9900) the Appellant billed on March 18, 2013.¹ The hearing record does establish the Appellant is entitled to coverage for the durable medical equipment (“DME”) and related supplies under Medicare Part B. The Appellant is entitled to payment for the covered services.

Procedural History

The Appellant submitted claims for charges relating to a NovoTTF-100A System (now known as Optune® TTFT)² and/or a monthly supply of insulated transducer arrays to Noridian Healthcare Solutions, the Medicare Administrative Contractor (“Contractor”) with jurisdiction. The Contractor denied the claim initially and on redetermination. C2C Solutions, Inc., the Qualified Independent Contractor (“QIC”), issued an unfavorable reconsideration decision on April 21, 2014.

On May 27, 2014, the Office of Medicare Hearings and Appeals (“OMHA”) received the Appellant’s timely request for an ALJ Hearing. 42 C.F.R. § 405.1014(c). This ALJ held a pre-hearing conference by telephone on January 25, 2018, and then a consolidated hearing by telephone on April 24, 2018.³ The Appellant appeared through its representative, Stephanie

¹ This ALJ notes that another ALJ issued a favorable decision on E1399 for the date of service of March 18, 2013. (Hearing testimony). This ALJ finds that he has proper jurisdiction to issue a decision on A9900 provided with a service date of March 18, 2013. *Id.*

² TTFT stands for tumor treatment field therapy.

³ This ALJ initially scheduled consolidated hearings for 50 cases. The Appellant voluntarily withdrew a number of cases prior to hearing and all remaining cases received a decision or consolidated decision per beneficiary. This

Hales (Esq.) of Sidney Austin, LLP. Justin Kelly (NP, Senior Director of Health Policy), and Sean Dias (Case Manager) appeared as witnesses on behalf of the Appellant. The Contractor elected to participate as a non-party participant, represented by Dr. Barbara O'Neal, M.D. and Dr. Fred Manuya, M.D. Exhibits 1-6⁴ were admitted into the record without objection. This ALJ carefully considered the testimony, arguments, and medical evidence.

Issues

The issues before this ALJ are those include all of the issues brought out in the initial determination, redetermination, and/or reconsideration that were not decided entirely in a party's favor and any additional issues specified in the request for hearing.

The issues are described in more detail in Section A of the Analysis.

Findings of Fact

After careful consideration of the entire record (Exhibit List attached and incorporated herein), a preponderance of the evidence establishes the following facts:

1. The Food and Drug Administration ("FDA") approved the Appellant's Pre-Market Approval ("PMA") application for the NovoTTF-100A System on April 8, 2011. (Exh. 1, pp. 22-26). The letter states:

This device is indicated for treatment of adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme, following histologically- or radiologically confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GB after surgical and radiation options have been exhausted.

(Exh. 1, p. 22).

2. The National Comprehensive Cancer Network ("NCCN") updated its guidelines addressing nervous system cancers in late 2012.⁵ The NCCN indicated a physician

ALJ held a second consolidated hearing for the Appellant and CGS on April 6, 2018. This ALJ is rendering a separate decision containing the appeal numbers for each of the Beneficiaries involved in the claims.

⁴ During the hearing, the hearing record was held open for specific submissions. The Appellant and Contractor were not permitted to submit additional medical records related to any of the Beneficiaries involved in this group of hearings. The Appellant provided copies of Articles discussing use of tumor treatment field therapy published in the Journal of American Medical Association in 2015, 2017, and 2018. This ALJ recognizes the articles were all published after the reconsideration decision. The Contractor submitted a pre-hearing position paper with multiple years of the NCCN guidelines. Following the hearing, the Contractor submitted additional articles and NCCN information. This ALJ finds good cause to admit the new evidence as Exhibit 6. 42 C.F.R. §§ 405.1018 and 405.1028.

⁵ See Journal of the National Comprehensive Cancer Network, at <http://www.jnccn.org/content/11/9/1114.full.pdf+html>.

should “consider alternating electric field therapy (for glioblastoma) (Category 2B).”⁶ (Journal of National Comprehensive Cancer Network, *Central Nervous Systems Cancers*, Vol. 11 No. 9, p. 1120 (Sept. 2013)).⁷

3. The Beneficiary was a 69 year-old male on the dates of service at issue. (Exh. 2, p. 25).
4. The Beneficiary was initially diagnosed with Grade IV, Glioblastoma Multiforme (“GBM”) in 2009. (Exh. 2, p. 25).
5. The Beneficiary underwent debulking in November 2009 followed by radiotherapy and temozolomide. (Exh. 2, p. 25). Upon evidence of disease progression, the Beneficiary was started on bevacizumab (Avastin). *Id.* The Beneficiary was then started on a clinical trial of ABT 888 in combination with Temodar. *Id.* Despite these efforts, the Beneficiary’s disease again progressed and he was told there were no more options. *Id.*
6. On March 7, 2013, the Beneficiary met with his physician. (Exh. 2, p. 25). After learning that NovoTTF was available the Beneficiary volunteered to be the first patient in the area and to serve as a model for the training staff. *Id.*
7. The Beneficiary underwent an MRI of the head with intravenous gadolinium on March 7, 2013, which showed an area of enhancement of GBM around the resection site. (Exh. 2, pp. 25-29). The physician noted that the Beneficiary had progressive relapsed glioblastoma. *Id.*
8. The Beneficiary received instruction on how to setup and use the NovoTTF-100A System on March 18, 2011. (Exh. 2, pp. 10-11).
9. The Beneficiary acknowledged receipt of various products, including a NovoTTF-100A System and 40 transducer arrays, on March 18, 2013. (Exh. 2, pp. 10-11).
10. The Beneficiary signed the Service Agreement, Patient Rights and Responsibilities Supplier Standards, Financial Review/Assessment, and information on how to file a complaint. (Exh. 2, pp. 9-24).
11. The physician signed a prescription and order form for the TTFT device and related supplies on February 14, 2013. (Exh. 2, pp. 4-5). The physician indicated the Beneficiary was diagnosed with “glioblastoma” (ICD-9 diagnosis code 191.9). *Id.* The physician signed the order, indicating he/she believed the NovoTTF-100A System and

⁶ The NCCN cited to the European Journal of Cancer, *NovoTTF-100A System versus physician’s choice chemotherapy in recurrent glioblastoma: a randomised phase III trial of novel treatment modality* (2012; 48: 2192-2202). (See also Exh. 3).

⁷ NCCN, at https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx.

A Category 2B designation is “based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate,” indicating that at least 50 percent but less than 85 percent of the panel/voting participants supported the treatment option at the time.

accessories/supplies continued to be medically necessary for an additional 6-month period. *Id.*

12. The medical record includes a Letter of Medical Necessity⁸ authored by Dr. M.D. on July 3, 2013. (Exh. 2, pp. 6-8). Dr. was seeking to “initiate NovoTTF treatment” and requesting a predetermination of coverage and payment for the device and supplies. (Exh. 2, p. 17). Dr. Nieva indicated the device was medically necessary since the Beneficiary had failed “systemic chemotherapy and all radiotherapy options approved for this clinical scenario” and was not a surgical candidate. (Exh. 2, p. 18).
13. The record contains invoices and claim forms listing charges for 40 units of transducer arrays at a submitted charge of \$14,000.00. (Exh. 2, pp. 1-3).
14. The hearing record does not contain an Advanced Beneficiary Notice (“ABN”) and the Appellant has waived all rights to charge and collect a fee for the service(s) at issue in this case.
15. At hearing, Ms. Hales argued the Appellant is entitled to coverage for the NovoTTF-100A System and/or arrays since the device fell within a defined benefit category and had been established as safe and effective for the treatment of recurrent glioblastoma multiforme (“RGBM”) at the time of the date(s) of service. (Hearing CD).
16. Ms. Hales argued the NovoTTF-100A System should be found medically reasonable and necessary when considering the requirements found in chapter 13 of the *Medicare Policy Integrity Manual*. *Id.* The FDA approval, the results of the 2011 European clinical trial (“EF-11 clinical trial”), and NCCN’s guideline changes support finding the device in question was safe and effective. *Id.* The FDA’s approval, the results of the EF-11 clinical trial, and NCCN changes indicate the device was no longer investigational. *Id.* The device was an appropriate treatment option given the fact that the device was widely accepted and was being used in more than 100 oncology centers in 2013. *Id.*
17. Ms. Hales argued payment for the NovoTTF-100A System and supplies were not bundled until 2014. *Id.* The Appellant is entitled to separate payment for the device and/or supplies for services rendered in 2013. *Id.*
18. Nurse Kelly stated the effectiveness of the NovoTTF-100A System is comparable to that of chemotherapy alone. (Hearing testimony of Nurse Kelly). The device provides a patient with a better quality of life compared to chemotherapy. *Id.* There is no systemic toxicity. The most common side effect of using the device is that a patient may develop a scalp rash or irritation where the arrays are attached to his/her scalp. *Id.*

⁸ The Letter of Medical Necessity contained in all of the cases heard are identical but for the first and second to last paragraphs tailored to identify the beneficiary involved in the specific case, his/her diagnosis, and identifying the clinic he/she received his/her care from. *See also* Redetermination and Reconsideration requests. (Exh. 1).

19. GBM is a rare, orphan brain cancer that affects a small portion of the population. *Id.* The initial treatment is for the patient to undergo surgical resection (when possible) followed by chemoradiation (up to dose limits) and adjuvant chemotherapy. *Id.*
20. GBM is an aggressive disease that recurs after the initial, and repeat, treatment. *Id.* A patient is diagnosed with RGBM by his/her treating physician⁹ following either a biopsy or imaging revealing the disease has returned or progressed. *Id.* Imaging, often by MRI, is more commonly used since the biopsy is a surgical procedure and most patients are not candidates for additional surgery. *Id.*
21. A patient historically is re-evaluated for further surgery, chemoradiation (up to dose limits), and chemotherapy (both initial and then maintenance). *Id.* A limited number of patients are appropriate for an additional surgery and chemoradiation treatment. *Id.* A patient typically will not survive longer than 5 months without treatment and around 12 to 14 months with treatment. *Id.*
22. The only FDA approved treatments for RGBM is the NovoTTF-100A System or possibly more Avastin¹⁰ (or other off-label chemo agents). *Id.* A patient's overall prognosis nevertheless remains grim. *Id.*
23. The FDA approved the Appellant's PMA application for the NovoTTF-100A System in April 2011, which is a stringent process that few devices pass. *Id.*
24. Nurse Kelly argued the TTFT treatment using the NovoTTF-100A System was a proven, established means of treating patients with RGBM prior to the date(s) of service. *Id.* The device was used in an EF-11 clinical trial involving 237 patients. *Id.* The trial revealed sufficient scientific evidence that the device was safe and as effective as chemotherapy. *Id.* The device resulted in no toxicity compared to chemotherapy. *Id.*
25. Nurse Kelly argued there was a medical consensus for the device on the date(s) of service. *Id.* The strongest literature supporting the Appellant's position is the 2012 article in the European Journal of Cancer written by Dr. Roger Stupp *et al.* *Id.* The NCCN updated the treatment guideline in late 2012 to include TTFT as an alternative treatment option for RGBM. *Id.* There were approximately 100 leading oncology centers in the United States who were certified to prescribe the device in 2013 (the number increased to hundreds more at later times). *Id.* Some private insurance companies were covering the device.¹¹
26. Nurse Kelly explained there have been favorable developments following the date(s) of service. *Id.* A second trial evaluated the use of the Optune with Temozolomide¹² for

⁹ The treating physicians may include the patient's oncologist, radiation oncologist, and/or brain surgeon.

¹⁰ Avastin is also known by the brand name Bevacizumab. This decision will only refer to Avastin for consistency.

¹¹ See Aetna, at http://www.aetna.com/cpb/medical/data/800_899/0827.html#dummyLink2.

¹² This ALJ recognizes Temozolomide is also known by the brand name Temodar. This decision will only refer to Temozolomide for consistency.

newly diagnosed GBM patients. *Id.* (see also Exh. 3). The FDA approved using the Optune with Temozolomide for newly diagnosed GBM in October 2015.¹³ *Id.* The NCCN has since reclassified the use of TTFT as a Category 1 treatment option.¹⁴ *Id.*

27. Nurse Kelly argued the NovoTTF-100A System was reasonable and necessary for this specific Beneficiary. (Hearing testimony, individual case audio). The Beneficiary was diagnosed with glioblastoma in 2009 and underwent debulking. *Id.* The Beneficiary developed recurrence in May of 2011 and underwent a second resection. *Id.* In August of 2012, the Beneficiary developed another recurrence. *Id.* Optune was FDA approved for the Beneficiary's condition. *Id.* The Beneficiary's compliance with the device during the date of service under review was 84%. *Id.*
28. The Appellant explained that this was the first date of service and the order reflects that the supplies were delivered to the Beneficiary on this date. (Hearing testimony).
29. The Contractor argued that a supplier is not entitled to Medicare Part B coverage merely based on the fact that an item has been classified as DME. (Hearing testimony). The Contractor and Appellant also generally discussed or agreed that later, prospective evidence was not the basis of the Contractor's review process and entitled to less weight. *Id.*
30. There was no national or local coverage decision when this claim was initially reviewed. *Id.* The claim was therefore analyzed by the Contractor under the requirements set out in Section 13.5.1 of Chapter 13 of the *Medicare Program Integrity Manual* ("MPIM"). *Id.*
31. The Contractor also argued the FDA's approved of the NovoTTF-100A System for RGBM does not entitle the Appellant to coverage. *Id.* (see also Exh. 5, p. 27; Exh. 5A, p. 12).
32. The Contractor's position is that the requirements outlined in the MPIM were not met. *Id.* The device did not result in meaningful improvement. *Id.* The device did not significantly prolong the patient's survival. *Id.* Any long-term side effects of using the device were unknown since the device had been used for less than 5 years. *Id.*
33. The Contractor stated the costs associated with the device and supplies were not considered when determining whether the device was medically reasonable and necessary. *Id.*

¹³ See U.S. Department of Health & Human Services, U.S. Food & Drug Administration, at <http://wayback.archive-it.org/7993/20170111141452/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm475607.htm>.

¹⁴ A Category 1 designation is "based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate," indicating at least 85 percent of the panel members voted in favor of the treatment option at the time.

34. The Contractor argued the literature the Appellant cited to does not support coverage for the NovoTTF-100A System. *Id.* The conclusions reached as a result of the EF-11 clinical trial should be considered invalid. *Id.* The Appellant was involved in designing the study and recruited patients that fit the hypothesis. *Id.* The study as a whole followed only 237 patients, some of which did not start treatment or dropped before the first cycle.¹⁵ *Id.*
35. The Contractor argued the effectiveness of the NovoTTF-100A System remained questionable. *Id.* The FDA panel involved in approving the device was split. *Id.* The device was approved with the chairperson's tie-breaking vote in favor of effectiveness. *Id.* The minutes indicate there was a significant debate about how effective the device was. *Id.* The NCCN did initially categorize TTFT as a Category 2B but downgraded the status to Category 3¹⁶ in 2014. *Id.* Thereafter, the status was restored to 2B in 2015, and then remained 2B through 2018.¹⁷
36. The Contractor argued the fact that an oncology center and/or physician are certified to use the device does not alone indicate general acceptance. *Id.* The certification does not mean the treatment method is being used at the center or by the physician. *Id.*
37. The Contractor explained that the trial relied on by the Appellant began as a superiority trial but was later switched to a non-inferiority trial. (Hearing testimony). Generally, a lot of emphasis is not placed on a study if halfway through the trial end points change. *Id.* The Contractor explained further that it would be interesting to see a palliative arm of the study. *Id.*

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¹⁵ The Contractor did acknowledge the small size may have been related at least in part to difficulty recruiting patients who were willing to participate in the trial.

¹⁶ A Category 3 designation is "based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate," indicating there was strong disagreement among the panel members but at least 3 panel members representing 3 different institutions voted in favor treatment option at the time.

¹⁷ Some draft/discussion comments to the NCCN in 2018 suggested there is a debate between Categories 2B and 3. The adopted guidelines continue to classify TTFT as Category 2B for the treatment of RGBM and a Category 1 treatment for newly diagnosed GBM.

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (“HHS”), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (“Act”) § 1869(b)(1)(A); *see also* 42 C.F.R. § 405.1014. The Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decision of the Secretary, unless the individual/organization appeals to the Medicare Appeals Council. *Id.*

A request for hearing is timely if it is received by OMHA within 60 days after the party received the reconsideration decision, unless the individual/organization establishes good cause to extend the time to file. 42 C.F.R. §§ 405.1002(a)(1) and 405.1014(c). The Appellant is presumed to have received the QIC’s reconsideration five days after the date noted on the first page of the reconsideration, unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3).

B. Scope of Review

The ALJ considers all issues not decided entirely in the party’s favor at any prior level of review. 42 C.F.R. § 405.1032(a). The ALJ assigned to hear this matter may give notice to the parties of any other issue will be addressed at the hearing. 42 C.F.R. § 405.1032(b). The ALJ may also issue a decision on the record at the request of a party and there are no other parties who wish to appear. 42 C.F.R. § 405.1038(b). The ALJ may also issue a decision on the record on his/her own initiative if the evidence in the record supports a fully favorable finding. 42 C.F.R. § 405.1038(a).

A party may not offer new evidence for the first time at the ALJ level of review unless good cause exists. 42 C.F.R. § 405.1018(c). The party must submit a statement explaining why the evidence not previously submitted. *Id.* The ALJ will examine the statement and evidence to establish whether good cause was established. 42 C.F.R. § 405.1028(a). This restriction is not applicable to unrepresented beneficiaries or oral testimony given during the course of a hearing. 42 C.F.R. § 405.1018(d).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue and makes a decision based on the evidence, without regard to the findings made by the lower levels on the claim. 42 C.F.R. § 405.1000(d). The Appellant bears the burden of proving each element of the Medicare claim. Act §§ 1814(a)(1), 1815(b), and 1833(e); *see also* 42 C.F.R. §§ 405.1018, 405.1028, 405.1030, and 424.5(a)(6).

II. Principles of Law

A. Statutes & Regulations

The statutory authority for the Medicare program is found in Title XVIII of the Act. 42 U.S.C. § 1395 *et. seq.* The Medicare program is divided in multiple parts. Medicare Part B is a voluntary insurance program that provides medical insurance benefits to “aged and disabled individuals” for services not covered under Medicare Part A (or Part D). Act § 1831. The individual must elect to enroll in the program. *Id.* The program is financed through contributions appropriated by the Federal Government in addition to premium payments. *Id.* The Secretary of the Department of Health and Human Services has the authority to promulgate regulations which define or clarify the provisions of the Act. 42 C.F.R. § 410 *et seq.*

Section 1832 of the Act establishes the scope of benefits that are provided to an eligible beneficiary under Medicare Part B. *See also* 42 CFR §§ 410.3 and 410.10. Section 1832(a)(2)(B) of the Act indicates an individual is entitled to have payment made on his/her behalf for medical and other health services furnished by a provider of services or by others under arrangement with a provider. Section 1861(s)(6) of the Act defines the term “medical and other health services” to include durable medical equipment. *See also* 42 CFR §410.36(a)(3).

Medicare coverage for DME is determined in one of three ways. The claim must be decided consistent with an applicable “National Coverage Determination” (NCD). Act § 1869(c)(3)(B)(ii)(I). If there is no applicable NCD, the decision maker is required to consider, though is not bound, by the Local Coverage Determination (“LCD”) for the geographical area at issue. Act § 1869(c)(3)(B)(ii)(II). If there is no NCD or LCD addressing the matter, the decision maker is required to decide the matter “based on applicable information, including clinical experience and medical, technical, and scientific evidence.” Act § 1869(c)(3)(B)(ii)(III); *see also* 68 Fed. Reg. 63693.

The regulations define durable medical equipment as follows:

Equipment, furnished by a supplier or a home health agency that:

- 1) Can stand repeated use.
- 2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- 3) Is primarily and customarily used to serve a medical purpose.
- 4) Generally is not useful to an individual in the absence of an illness or injury.
- 5) Is appropriate for use in the home.

42 CFR § 414.202.

Section 1834 of the Act defines the rules for payment of durable medical equipment. *See also* 42 C.F.R. §§ 410.38(g) and 414.210.

Medicare may not make a payment under Part A or Part B for anything which is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of

a malformed body member. Act § 1862(a)(1)(A); *see also* 42 C.F.R. §§ 411.15(k) and 414.200 *et seq.* A provider or supplier is responsible for providing sufficient documentation to support the services were medically necessary, the services were provided as bill, and that payment is due. Act §§ 1833(e); *see also* 42 C.F.R. § 424.5(a)(6).

In the event the services are found to be “not medically reasonable and necessary” or “custodial in nature” under Section 1862(a)(1) or (9) of the Act, Section 1879 of the Act provides for limitation on liability for Medicare payments. The regulations address how to determine if the beneficiary or provider/supplier had the requisite degree of knowledge to make them liable under Section 1879 of the Act. 42 C.F.R. § 411.400 *et seq.*; *see also HCFA Ruling 95-1*. If a beneficiary has no knowledge that the services would not be covered, but the provider/supplier of the services did, then the provider/supplier is liable and cannot seek or retain payment made by or on behalf of a beneficiary. 42 C.F.R. § 411.404. In general, the existence of a notice, manual, or community medical standard is sufficient to constitute finding the provider/supplier had notice. 42 C.F.R. § 411.406.

B. Policy and Guidance

Unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than a NCD, can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. Act § 1871(a)(2); *see also* 42 C.F.R. § 405.1060. An NCD is the Secretary’s determination on Medicare coverage for a particular item or services applied nationally. 42 C.F.R. § 405.1060(a). An ALJ is bound by the NCD and required to ensure the NCD is applied correctly when applicable. 42 C.F.R. § 405.1060(a), (b).

The Secretary has not issued an NCD specifically addressing the DME, or the related supplies, at issue in this case. CMS, *Medicare National Coverage Determinations (Internet-Only Manual Publ’n 100-03)*, ch. 1. *See* NCD § 280.1 *et seq.* regarding DME coverage in general.

CMS and its contractors are permitted to issue policy guidance describing criteria for coverage and payment of selected items and services. 42 C.F.R. § 405.1062. This guidance is located in Medicare’s manuals and local coverage determinations (“LCD”). An ALJ is not bound by the policies outlined in a manual or LCD but is required to give the guidance substantial deference when applicable. 42 C.F.R. § 405.1062(a). An ALJ may decline to follow the guidance but must explicitly explain the reason(s) why. 42 C.F.R. § 405.1062(b). The ALJ’s decision not to follow the policy applies only to the specific claim being considered and has no precedential effect on other claims. *Id.*

CMS and CGS Administrators had not published a LCD addressing the DME and related supplies as of the date(s) of service at issue.¹⁸

¹⁸ The Contractor did not draft an LCD addressing the NovoTTF-100A System and publish it for comments until after the date(s) of service.

The *MPIM* indicates the Contractor is required to make individual claim determinations in the absence of an NCD and LCD. *MPIM (Internet-Only Manual Publ'n 100-08)*, ch. 13 § 13.3 (Jan. 2013). The decision is to be based on the medical reviewer's clinical judgement in light of the reasonable and necessary provisions outlined in Section 13.5.1. *Id.*

Reasonable and Necessary

Contractors shall describe in the draft LCD the circumstances under which the item or service is reasonable and necessary under 1862(a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
 - o Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
 - o Furnished in a setting appropriate to the patient's medical needs and condition;
 - o Ordered and furnished by qualified personnel;
 - o One that meets, but does not exceed, the patient's medical need; and
 - o At least as beneficial as an existing and available medically appropriate alternative.

There are several exceptions to the requirement that an item or service be reasonable and necessary for diagnosis or treatment of illness or injury. The exceptions appear in the full text of § 1862(a)(1).

MPIM, ch. 13 § 13.5.1; *see also Almy v. Sebelius*, 679 F.3d 297, 299 (4th Cir. 2012).

The Contractor is required to use the "strong evidence available." *MPIM*, ch. 13 § 13.7.1.

In order of preference, LCDs should be based on:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
- General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
 - o Scientific data or research studies published in peer-reviewed medical journals;
 - o Consensus of expert medical opinion (i.e., recognized authorities in the field); or
 - o Medical opinion derived from consultations with medical associations or other health care experts.

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general

acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

Id.

The *Medicare Benefits Policy Manual* ("MBPM") defines reasonableness and necessity with regard to DME specifically. *MBPM (Internet-Only Manual Publ'n 100-2)*, ch. 15, § 110 (Oct. 2003). An item classified as DME will not be covered in every instance." *MBPM*, ch. 15, § 110.1.C. The item(s) must be "necessary and reasonable for treatment of an illness or injury, or to improve the functioning of a malformed body member." *Id.* The *MBPM* states:

1 - Necessity for the Equipment

Equipment is necessary when it can be expected to make a meaningful contribution to the treatment of the patient's illness or injury or to the improvement of his or her malformed body member. In most cases the physician's prescription for the equipment and other medical information available to the DMERC will be sufficient to establish that the equipment serves this purpose.

2 - Reasonableness of the Equipment

Even though an item of DME may serve a useful medical purpose, the DMERC or intermediary must also consider to what extent, if any, it would be reasonable for the Medicare program to pay for the item prescribed. The following considerations should enter into the determination of reasonableness:

1. Would the expense of the item to the program be clearly disproportionate to the therapeutic benefits which could ordinarily be derived from use of the equipment?
2. Is the item substantially more costly than a medically appropriate and realistically feasible alternative pattern of care?
3. Does the item serve essentially the same purpose as equipment already available to the beneficiary?

3 - Payment Consistent With What is Necessary and Reasonable

Where a claim is filed for equipment containing features of an aesthetic nature or features of a medical nature which are not required by the patient's condition or where there exists a reasonably feasible and medically appropriate alternative pattern of care which is less costly than the equipment furnished, the amount payable is based on the rate for the equipment or alternative treatment which meets the patient's medical needs.

The acceptance of an assignment binds the supplier-assignee to accept the payment for the medically required equipment or service as the full charge and the supplier-assignee cannot charge the beneficiary the differential attributable to the equipment actually furnished.

Id.

The *MPIM* identifies what documentation a supplier is required to retain for at least a 7-year period. *MPIM*, ch. 5. The supplier is required to have an order from the physician prior to delivering the DME and/or related supplies. 42 C.F.R. § 410.38; *MPIM*, ch. 5, §§ 5.2.1, 5.2.2, and 5.2.3. The supplier must obtain a detailed written prior to filing a claim. *Id.* The supplier is required to maintain proof of delivery. *MPIM*, ch. 4, § 4.26.1 and ch. 5, § 5.8.

All Medical records must be authenticated by the author. *MPIM*, ch. 3, § 3.3.2.4. The method used shall be a handwritten or electronic signature, as stamped signatures are not acceptable. *Id.*

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ANALYSIS

A. INTRODUCTION AND ISSUES

This ALJ with jurisdiction conducted a *de novo* review of the evidence to first determine if the NovoTTF-100A System¹⁹ is medically reasonable and necessary in general for the treatment of recurrent GBM (“RGBM”).²⁰ The dates of service in this case, and all the related cases held during the consolidated hearing, involve the 2013 calendar year. Thus, this general determination turns on whether the NovoTTF-100A System was merely investigational and experimental in 2013 or if it had been proven safe and effective, was widely accepted by the medical community, and appropriate for the treatment of RGBM in 2013. This general topic shall be referred to as the “Investigational and Experimental Issue,” as it was at the prehearing conference and during the hearing, and is located in Section C.²¹

Second, for each specific patient in this series of cases, this ALJ reviewed the specific medical reasonableness and necessity of the treatment for the Novo-TTF-100A System in Section D.

Third, some cases in the hearing group also involved additional case-specific issues, such as whether there was manufacturer pricing information in the record, whether the arrays were separately payable and coded in 2013, or whether there was proof of delivery. These specific issues will be identified and resolved on a case by case basis in Section E. In this particular case, the additional issues raised relate to the proof of delivery issue. (Exh. 1, pp. 1-7).²²

Lastly, the discussion of any liability allocation can be found in Section F.

B. SUMMARY OF RESULT IN THIS SPECIFIC CASE

This ALJ has determined that the NovoTTF-100A System, and related transducer arrays, was more than investigational and experimental, and generally an acceptable form of last resort medical treatment for RGBM in 2013 for appropriate patients. The DME status of the device at issue is not contested. The medical record contains a physician’s order for the device and supplies, adequate proof of manufacturer pricing, and proof of delivery. The Appellant thus prevails on the threshold issues. However, in this specific matter, this ALJ is FAVORABLE on the specific merits of coverage. The NovoTTF-100A System and insulated transducer arrays were medically reasonable and necessary as applied to this Beneficiary.

¹⁹ The NovoTTF-100A System is a piece of durable medical equipment and the insulated transducer arrays are a required supplies for the system. The device is now known under the name, Optune® TTFT.

²⁰ The term ‘progressive’ is used interchangeably with ‘recurrent’.

²¹ As an aside, there is no question, and acceptance by CMS that the device is at least Durable Medical Equipment (DME) so that is discussed only briefly in Section C. Similarly, no NCD or LCD directly on point existed during the dates of service, and so discussion of the same is minimal and reference to sub-regulatory guidance is primary to applicable CMS Manuals.

²² For efficiency, this ALJ will present the QIC and Contractor’s additional reasons for denying the claim harmoniously in a joint presentation.

C. GENERAL NECESSITY – WAS THE NOVOTTF-100A SYSTEM ‘INVESTIGATIONAL AND EXPERIMENTAL’ FOR THE TREATMENT OF RGBM IN 2013?

NovoTTF-100A System meets the definition of DME (But Analysis Must Continue)

In general, for an item of DME to be covered by Medicare, it must be eligible for a defined Medicare benefit category, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and meet all other applicable statutory and regulatory requirements. Act § 1862(a)(1)(A). The documentation must demonstrate the DME, and supplies, satisfy the medical reasonable and necessary standard. *MPIM*, ch. 5, § 5.7. The *MPIM* states the medical records should include information about a patient’s diagnosis and other pertinent information to substantiate medical necessity for the type and quantity of items ordered as well as the frequency of use and replacement. *MPIM*, ch. 5, §§ 5.7 and 5.8.

A supplier is required to maintain a record of the dispensing order, the detailed written order, Certificate of Medical Necessity or DME Information Form (if applicable), and proof of delivery in addition to information related to a beneficiary’s diagnosis. *MPIM*, ch. 5, § 5.8; *see also MPIM*, ch. 5, §§ 5.2 and 5.3. If the information in the patient’s medical record does not adequately support the medical necessity for the item, or there is missing documentation, the supplier is liable for the cost of the item absent a valid Advance Beneficiary Notice. *MPIM*, ch. 5, §§ 5.7 and 5.8; *see also* Act § 1833(e) and 42 C.F.R. § 424.5(a)(6).

It is uncontested that the NovoTTF-110A System is DME that falls within a defined benefit category. CMS issued an interpretation or bulletin to this effect in July 2013.²³ However, as the Contractors (and Appellant) correctly pointed out, the mere status that the NovoTTF-100A System was accepted as a piece of DME is not the primary inquiry in this case, and insufficient alone to achieve coverage.

General Medical Necessity

Evaluating Medical Necessity in General

In this case, there was no formal guidance in the form of an NCD or LCD addressing the DME (and supplies) at issue on the date(s) of service. Section 522 of the Benefits Improvement and Protection Act permits a contractor to issue a decision addressing whether and in what circumstances an item or service is covered as reasonable and necessary under Section 1862(a)(1)(A) of the Act. *MPIM*, ch. 13, §§ 13.1.3 and 13.5.1. The *MPIM* indicates the contractor “shall consider a services to be reasonable and necessary if the contractor determines that the services is:” (1) safe and effective; (2) not experimental or investigational; and (3) appropriate. *Id.* The contractor is to consider all applicable information when making a

²³ See NCD 280.1 generally.

determination on a claim in those cases where there is no applicable NCD or LCD. Act § 1869(c)(3)(B)(i)(III).²⁴

TTFT Treatment is Safe, Effective, and Not Investigational or Experimental

This ALJ considered the hearing record and finds the Appellant's arguments with the witness testimony and publications indicate using the NovoTTF-100A System to treat RGBM was medically reasonable and necessary in 2013 since the device was safe, as effective the chemotherapy alternative, and not investigational/experimental.

The Appellant's argument and witness testimony meanwhile focused on the initial PMA showing that the NovoTTF-110A System was proven at least as good as continued/repeat chemotherapy with Avastin or other agents. The NovoTTF-100A System resulted in a substantially better quality of life given the device resulted in fewer adverse side effects. For example, the NovoTTF-110A System usually only presents a skin rash as a typical side effect compared to the well-known systemic damage chemotherapy can cause.²⁵

This ALJ independently reviewed the articles the Appellant provided and finds they support the Appellant's position that the NovoTTF-100A System is safe and effective for the treatment of RGBM. (Exh. 3). The Appellant provided this ALJ with various articles initially documenting changes observed in the cell structure, animal trials followed by a Phase I human trial with the NovoTTF-100A. (Exh. 3). The initial human clinical trial was comprised of 10 individuals diagnosed with RGBM and was successful for its purpose.²⁶

Thereafter, and more central to this case, the significantly larger EF-11 clinical trial was then held prior to the dates of service. The clinical results were published in the *European Journal of Cancer* in 2012. (Exhs. 1-3, and Hearing CD).²⁷ The EF-11 clinical trial initially comprised with 237 patients with RGBM was concluded in 2011.²⁸ Of the 237 patients, 120 patients from 28 institutions over 7 countries were scheduled to receive TTFT treatment. Ninety-three of these patients completed at least 1 cycle, or 4 weeks of TTFT treatment. The remaining 117 patients were scheduled to receive chemotherapy treatment, and all but one patient completed one cycle.

²⁴ NCD, ch. 1, § 280 *et seq.*, governs DME in general. There are no provisions addressing TTFT.

²⁵ Familiarity with the detailed, multi-hour general hearings are assumed, and cited *passim*. This is a mere paraphrase and not intended as a complete list of the parties/participant's respective testimony. *See* Findings of Facts for more details. The hearing arguments and testimony also included substantial discussions about the nature of the PMA process, the PMA vote and subsequent events. These statements were considered and are discussed below.

²⁶ *See* articles, *Disruption of Cancer Cell Replication by Alternating Electric Fields*, *Alternating electric fields arrest cell proliferation in animal tumor models and human brain tumors*, and *TTFields alone and in combination with chemotherapeutic agents effectively reduce the viability of MDR cell sub-lines that over-express ABC transporters*. A clinical trial involved 20 individuals, 10 of which were diagnosed with RGBM patients. *See also* articles, *Chemotherapeutic treatment efficacy and sensitivity are increased by adjuvant alternating electric fields*; *Tumor treating fields: concept, evidence and future*; and *NovoTTF-100A: a new treatment modality for recurrent glioblastoma*.

²⁷ *See* article, *NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma; a randomised phase III trial of a novel treatment modality*, *Eur. J. Cancer* (2012) 48, 2192-2202, Roger Stupp, *et al.*

²⁸ One article does indicate 8 percent of the patients reportedly had a history of a lower grade glioma prior to being diagnosed with RGBM.

The overall survival rate of patients treated with TTFT was not superior but was comparable to the overall survival rate of patients treated with chemotherapy. Similarly, the FDA's pre-market approval of TTFT for RGBM in April 2011 was based on the FDA's conclusion, in its Summary of Safety and Effectiveness Data document, that "NovoTTF-100A treatment exhibits minimal toxicity, clinically comparable primary and secondary effectiveness and better quality of life compared to the chemotherapies in the control arm of the study."²⁹

Moving on to the hard data, the EF-11 clinical trial indicated 20 percent of patients from each treatment group were alive after 1 year. The results dropped to eight percent of TTFT patients alive at the end of two years in contrast to five percent of patients treated with chemotherapy. The results fell to four percent and one percent at the end of year three respectively.³⁰

Thus, this ALJ finds the studies collectively indicate TTFT treatment was safe and at least as effective as chemotherapy to treat RGBM. The most common side effect of the TTFT was scalp dermatitis, a relatively minor side effect which could be addressed with steroids and adjusting the placement of the arrays. Another theoretical side effect of the TTFT could be a neurological disorder, but this did not feature in the record(s) or unduly concern the FDA, and most neurological deterioration would be logically related to the underlying RGBM.

The medical community's acceptance of the NovoTTF-100A System as a means of treating RGBM supports the Appellant's argument that the device was safe and effective in 2013. The FDA approved the Appellant's PMA in April 2011 for RGBM. This ALJ recognizes the panel of 12 physicians were split 6-6 on whether the device was effective.³¹ The chairperson's vote resulted in the panels' ultimate recommendation. The FDA presumably at least in part relied on the recommendation when it approved the PMA. To date, the FDA has never withdrawn the approval, or issued any warnings.

The NCCN did not immediately add TTFT treatment to its guidelines in 2011. The guidelines were changed to add TTFT as a treatment option in late 2012, or more than a year after the FDA's approval. This ALJ finds the Appellant has established by a preponderance of the evidence indicates the NovoTTF-100A System was safe and effective for the treatment of RGBM.

This ALJ considered the testimony offered by the Contractor. The Contractor's testimony focused on the effectiveness of the NovoTTF-100A System. The Contractor raised multiple concerns about how the EF11 study (and the initial study) were conducted. In part, the Contractor thought the *n* value, or number of participants, of the study arms were relatively small. The EF-11 clinical trial was only comprised of 237 total participants, of which 120 of those participants were scheduled to receive TTFT monotherapy. Only 93 of the original 120

²⁹ FDA PMA P100348, p. 38 (April 8, 2011).

³⁰ This ALJ did not focus on any mortality difference because the Appellant did not argue this point. The mean survival rate was possibly higher in those patients treated with TTFT as opposed to chemotherapy with respect to those RGBM patients in whom Avastin failed (which was not the direct focus of the EF11 study).

³¹ The panel voted unanimously that the device was safe. The panel ultimately recommended the NovoTTF-100A with a 7-3 vote (two members abstained from voting).

participants started and completed 4 weeks of treatment, or one cycle. Additionally, the EF11 trial was initially slated as a superiority study before it was switched to a non-inferiority study, and the Contractor questioned the lack of a palliative arm in the EF11 trial. However, the Contractor did not contend there were any safety concerns with using TTFT or disagree that TTFT was systemically gentler than chemotherapy for the patient.

The Contractor's witnesses raised reasonable and thoughtful points, but this ALJ thinks the Appellant's case (and burden of proof) is strong enough, e.g. a civil preponderance of the evidence, to rebut or survive those concerns. In part, this ALJ does not agree with the Contractors' argument that the results should be considered invalid merely because the EF-11 clinical trial consisted of only 237 patients split into 2 arms. GBM is an aggressive, fatal orphan disease that only affects a small fraction of the population. About 10,000 individuals are diagnosed with GBM each year. An "n" value greater than 30, and even 60 and 90, appears sufficient to provide statistical evidence that using the NovoTTF-100A system was non-inferior to chemotherapy.³² Furthermore, 93 patients in the TTFT arm that completed at least one cycle represented a little more than 2.5 percent of individuals diagnosed with GBM each year. The population used was significant given the aggressive nature of the disease and high mortality rate.

In addition, the fact that physicians associated with the Appellant were involved in the EF-11 clinical trial does not negate or diminish the ultimate findings. The hearing record suggests the NovoTTF-100A System was the only TTFT device being developed at the time. It is reasonable the Appellant would maintain some degree of involvement in the EF-11 clinical trial (and subsequent trials) to ensure the device was being used properly to achieve the most accurate results, and because of the linked practical reality of needing manufacturer/developer involvement when testing a piece of DME.

Finally, the fact that the EF-11 clinical trial was converted from a superiority study to non-inferiority study with no palliative arm does not suggest the results should be considered unreliable. The decision to change was sufficient since it afforded the participants greater safety and comfort. Entitled to heavy weight as well, is that the FDA, through the PMA process, actually directed the Appellant to change to a non-inferiority study for the best interests of the patients. The use of a palliative arm would also have been impractical and ethically challenging given the diagnosis. It would likely have been difficult to recruit a large number of RGBM patients willing to only accept hospice care.

This ALJ recognizes the Appellant and Contractor are in agreement that the NovoTTF-100A System does provide a patient with a higher quality of life ("QOL") and fewer side effects compared to chemotherapy. A patient's pursuit for medical-related QOL is a meritorious clinical goal, and a highly individual choice. This result dovetails with this ALJ's ultimate determination that the NovoTTF-100A System is non-inferior to chemotherapy while offering a

³² This ALJ finds the size of the sample reasonable since GBM is an orphan disease. This ALJ agrees with the Appellant's argument that it would be unreasonable to require a larger study typical for common diagnoses involving millions of potential patients, such as in cardiac disease and related intervention procedures, stroke, diabetes mellitus and chronic obstructive pulmonary disease.

substantially higher QOL. The device is covered as a last resort treatment option for appropriate individuals diagnosed with RGBM for whom the device meets the statutory structure of reasonable and necessary as outlined under Medicare Part B.

In summary, multiple clinical trials evaluating the effects of the NovoTTF-100A System on patients with RGBM had concluded by 2011. The FDA approved the Appellant's PMA to use the NovoTTF-100A System to treat patients with RGBM. This ALJ finds the hearing record demonstrates as a whole that the NovoTTF-100A System was no longer experimental or investigational for treating RGBM.

However, discussed in more detail below, this ALJ rejects expanding or limiting coverage based on events that occurred after 2013. One of the Appellant's arguments is that the NovoTTF-100A System is appropriate for *other* diagnosis. The FDA, and NCCN, has since expanded the use of the Optune as part of the frontline treatment after a patient is initially diagnosed with GBM. Some of the Appellant's claims indicate the NovoTTF-100A System was prescribed to treat other central nervous system cancers. The Appellant has not provided evidence the medical community supported a broader use for these additional diagnoses in 2013. Similarly, this ALJ has not disallowed coverage based on the LCD published after the date(s) of service.

Appropriateness & Sufficient Medical Community Acceptance

The hearing record as a whole demonstrates the NovoTTF-100A System was an appropriate treatment option for RGBM on the date(s) of service. This ALJ specifically focused on three of the listed areas: furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of RGBM, whether the device was just as effective as the best practices standard, and how frequent the device was used during a given period. *MPIM*, ch. 13, § 13.5.1.

First, the hearing record does demonstrate the accepted standard of medical practice for the treatment of RGBM in 2013 included the NovoTTF-100A System. The Appellant argued the 12-person panel convened by the FDA unanimously voted the device was safe and half of the panel was persuaded that the device was effective. (Hearing testimony). The FDA considered the panel's recommendation when it approved the Appellant's PMA. *Id.* The NCCN amended the guidelines for the treatment of RGBM in late 2012 to include TTFT. *Id.* Commercial insurance companies were starting to cover the device for RGBM. *Id.* As of 2013, about 100 oncology centers were certified to prescribe the device. *Id.*

The Contractor argued the NovoTTF-100A System was not the accepted standard of medical practice. The FDA's approval of the device does not mean the device is covered under Medicare. *Id.* One cannot conclude that because a center is certified that the physicians associated with that center are prescribing the device. *Id.* The NCCN subsequently downgraded the category to Category 3 in 2014 (before raising it back to 2B in 2015). *Id.* The Contractor located no published policies that indicated a commercial insurance provider was covering the device when it initially evaluated the claim. *Id.*

This ALJ is moved by the fact that the FDA approved the Appellant's PMA application in 2011, and had been in effect for nearly two years before the date(s) of service. This ALJ is further

moved by the fact that the NCCN changed its guidelines. The Category 2B status in effect during the date(s) of service indicates that no less than half the NCCN panel members were persuaded the NovoTTF-100A System was a treatment option for RGBM. The NCCN cited to the FDA approval and EF-11 clinical trial. "Similar survival was observed in the arms, and TTF therapy was associated with lower toxicity and improved quality of life." The NCCN's recommendation in 2013 for RGBM reads:

Patients should be followed closely with serial MRI scans (at 2-6 weeks post-RT, then every 2-4 months for 2-3 years, then less frequently) after the completion of RT. Because RT can produce additional BBB dysfunction, corticosteroid requirements may actually increase therefore, scan may appear worse during the first 3 months after completion of RT, even though no actual tumor progression is present. Early MRI scans allow for appropriate titration of corticosteroid doses, depending on the extent of mass effect and brain edema. Later scans are used to identify tumor recurrence. Early detection of recurrence is warranted, because local and systemic treatment options are available for patients with recurrent disease. However MR spectroscopy, MR perfusion, or PET can be considered to rule out radiation-induced necrosis or "pseudoprogression."

Management of recurrent tumors depends on the extent of disease and patient condition. For local recurrence, repeat resection, with or without wafer placement in the surgical bed, can be performed if possible. After resection, or if the local recurrence is unresectable, patients with poor PS should undergo palliative/best supportive care without further active treatment. If PS is favorable, systemic chemotherapy may be administered (especially for anaplastic oligodendroliomas); reirradiation is a category 2B option to consider if prior radiation procedures a good/durable response. Patients with recurrent glioblastoma may also consider alternating electric field therapy (category 2B). In the case of diffuse or multiple recurring lesions, the options are: 1) palliative/best supportive care for patients with poor POS; 2) systemic chemotherapy; 3) surgery to relieve mass effect; or 4) consider alternating electric field therapy for glioblastomas (category 2B).

All patients should receive best supportive care.

Furthermore, some commercial insurance companies were starting to cover the NovoTTF-100A System for RGBM as of the date(s) of service. Aetna began covering the device on March 19, 2013. Humana started covering the device the following a month. This ALJ finds the Appellant has persuasively demonstrated by a preponderance of the evidence that the NovoTTF-100A System had been accepted by the medical community as a treatment option for RGBM.

Secondly, the hearing record demonstrates the NovoTTF-100A System was at least as effective as the best practices standard, or chemotherapy. The Appellant argued the results of clinical studies revealed the NovoTTF-100A System was as effective as chemotherapy. (Hearing argument/testimony). The device resulted in less physical adverse symptoms compared to chemotherapy. *Id.*

This ALJ considered the arguments and testimony with the language of the *MPIM*. The effectiveness of the NovoTTF-100A System being as good as chemotherapy with less severe side effects is "meaningful improvement" within the meaning of the *MPIM*. Additionally, this ALJ does not read the *MPIM* to require TTFT result in a meaningful improvement beyond

established treatment options that are already covered by Medicare. *MPIM*, ch. 13, § 13.5.1. The language clearly states “at least as beneficial” as existing treatment options is sufficient, a standard which is met. *Id.* The Appellant has presented evidence that the EF-11 clinical trial revealed individuals treated with the NovoTTF-100A System had the same overall survival rate at the end of year 1 as those treated with chemotherapy. The overall survival rate at the end of years 2 and 3 was higher for those patients treated with the NovoTTF-100A System compared to chemotherapy.

This ALJ finds the Appellant has demonstrated by a preponderance of the evidence that the NovoTTF-100A System is at the very least as effective as chemotherapy to treat RGBM, safe and with less side effects, and satisfies the *MPIM* as a treatment option for RGBM (when medically necessary for the specific patient).

Additionally, this ALJ considered the appropriate frequency for the NovoTTF-100A System with regard a patient’s compliance. This issue was not specifically addressed during the global argument/testimony. (Hearing testimony). Ms. Hales’ statements and Nurse Kelly’s testimony addressed each of the Beneficiaries’ compliance when summarizing the specifics of each case. (Hearing testimony, individual case audio). The articles indicate the clinical trials involved the participants using the NovoTTF-100A System 18 hours a day on average. (Exh. 3). The Appellant’s Product Dossier clearly indicates “the recommended average daily use is at least 18 hours.” *Id.* This ALJ finds the NovoTTF-100A System is appropriate for daily use, with the expectation that a patient will use it 18 hours a day on average, or roughly 75 percent of the time.

Changes Following the Date(s) of Service Considered but Given Much Less Weight

There have been significant changes related to the NovoTTF-100A System since 2013. CMS assigned the NovoTTF-100A System a payment classification designation effective on January 1, 2014. The Appellant had billed the NovoTTF-100A System under miscellaneous HCPCS code E1399 and the insulated transducer arrays under miscellaneous supply HCPCS codes A9900 and A9999. CMS assigned HCPCS codes E0766 and A4555 to the device and arrays respectively. Payment for both the device and arrays would be bundled under E0766.

The FDA expanded its approval of the Optune, the second generation of the NovoTTF-100A System. The Appellant filed a supplement PMA application on April 10, 2015. The FDA approved the PMA on October 5, 2015. The FDA’s approval permitted using the Optune with Temozolomide “for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy.”

The NCCN has updated the guidelines related to RGBM on multiple occasions. The category was initially downgraded in 2014 to a “3,” indicating there was major disagreement that the intervention was appropriate.³³ The use of TTFT was upgraded back to Category 2B around April 2015. The use of TTFT remains at a Category 2B for RGBM while the treatment option is a Category 1 for newly diagnosed GBM.

³³ The change may reflect the consensus of those on the panel at the time.

A number of JAMA articles³⁴ in 2015, 2017 and 2018, in part reporting on the EF-14 study, have also emerged that support in randomized clinical trials, that TTFT (plus Temozolomide) is preferable to Temozolomide alone as a therapy for newly diagnosed glioblastoma. However, this ALJ does not think the JAMA articles change the central analysis or result in this case given the RGBM context.

Meanwhile, the Contractors collectively issued a local coverage determination, *LCD L34823*, in October 2015. *Local Coverage Determination L34823: Tumor Treatment Field Therapy (LCD L34823)*. The LCD indicates that tumor treatment field therapy “will be denied as not reasonable and necessary.” *Id.* The LCD includes no discussion of the analysis outlined in the *MPIM*. *Id.* The comments and responses suggest the decision not to cover the DME was because: 1) the FDA panel was evenly split on the question of efficacy with the chairperson’s vote breaking the tie; 2) the NCCN’s categorization of 2B indicated there was a consensus but the consensus was not uniform; and 3) the Compendia’s failure to include a narrative discussing the 2B category indicates those items do not fit Medicare’s definition of “generally medically accepted” category. *Id.*

This ALJ duly considered the changes that occurred after the date(s) of service but afforded the information little weight. This ALJ recognizes the FDA did broaden the PMA to use TTFT for individuals newly diagnosed with GBM, which is not at issue in the cases before this ALJ. The Contractor issued the initial version of the LCD days before the October 2015 approval. The LCD has been revised but continues to deny coverage for TTFT without discussing why the device is not medically reasonable and necessary in any circumstance while commercial insurance companies permit coverage in certain circumstances. Notably, this ALJ reviewed the sources the Contractors considered and found the FDA’s 2015 approval of the Appellant’s supplemental PMA was not considered. The Contractor has not cited to more recent publications.

Nevertheless, these events occurred following the date(s) of service and this ALJ finds it would be inappropriate to decide these cases prospectively. This ALJ focused on the information available on the date(s) of service when determining the use of the NovoTTF-100A System was medically reasonable and necessary for appropriate patients (addressed previously).

Specific Requirements Needed to Demonstrate Medical Necessity

This ALJ considered the Appellant’s arguments, the literature the Appellant provided, and the witnesses’ testimony when establishing the specific requirements for coverage of the NovoTTF-100A System and/or insulated transducer arrays. This ALJ has taken judicial notice of information published by the federal agencies and the NCCN.

The Appellant’s burden is to prove by a preponderance of the evidence that the documentation submitted with the claim(s) satisfies six requirements. The Appellant’s basic argument is that Medicare should cover the NovoTTF-100A System since the FDA approved the device prior to the date of service. This ALJ agrees in general with the Appellant’s argument and finds coverage for the NovoTTF-100A System is medically necessary if the factors identified in the April 2011

³⁴ The Journal of the American Medical Association.

PMA are present. Moreover, this result is consistent with the information in the Product Dossier and the NCCN guidelines in effect in 2013. (Exh. 3; Exh. 6). However, to the degree, if any, that the Appellant might contend this case (involving older dates of service and before subsequent broadening modifications to the FDA approval or NCCN guidelines) would allow an approval broader than the April 2011 PMA, this ALJ does not reach that far for these dates of service. The April 2011 PMA approval states in pertinent part:

This device is indicated for treatment of adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme, following histologically- or radiologically confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GB after surgical and radiation options have been exhausted.

(Exh. 1, p. 22).

This ALJ finds the approval itself appears to contain five separate requirements. The requirements are as follows:

- 1) the individual must be at least 22 years old;
- 2) the individual's medical history includes a diagnosis of GBM;
- 3) there is histological or radiological evidence of RGBM in the supratentorial region of the brain after the individual received chemotherapy;
- 4) the individual is not a candidate for further surgery or radiation; and
- 5) the TTFT is being used as a monotherapy.

These requirements are also consistent with the information in the Product Dossier and the NCCN guidelines in effect in 2013. (Exh. 3; Exh. 6).

With regard to the third (and any other impacted elements), this ALJ has required the medical record contain proof of histological or radiological evidence of RGBM in the supratentorial region of the brain after an individual has received chemotherapy. However, this ALJ has permitted some flexibility with regard to how this proof is documented. This ALJ will not require the medical record contain the actual imaging report that revealed recurrence in the supratentorial region of a patient's brain following chemotherapy. The Appellant only needs to provide a treatment note, progress note, or supplemental statement in the medical record (a supplier statement alone is insufficient) that addresses the findings.

This ALJ recognizes there might be instances where the medical record indicates a patient received Avastin (or a similar chemotherapy) while he/she was prescribed and using the NovoTTF-100A System. Avastin is the only other FDA approved treatment for RGBM. It is reasonable a physician may recommend and a patient elects to complete his/her then-current cycle of chemotherapy while he/she begins using the NovoTTF-100A System. This ALJ recognizes, as outlined in the April 2011 FDA PMA, the device is intended to be a monotherapy to treat RGBM. This ALJ will permit coverage for the device in those instances where the chemotherapy was started prior to a physician's order for the device and the chemotherapy is stopped at the end of the. Coverage will be denied if the medical record suggests the two are

being used a polytherapy, i.e. an additional cycle is started or chemotherapy is added to a patient's treatment regimen at the same time or after the physician ordered the device.

The sixth and final requirement is compliance. The Appellant's Product Dossier and the articles indicate the ideal treatment is for a patient to use the NovoTTF-100A System 18 hours a day on average. (Exh. 3). This ALJ has relied on this information when finding the medical record should demonstrate a patient used the device about 75 percent of the time prior to and/or during the dates of service. The medical record must specifically address a patient's compliance prior to and/or during the dates of service but some oral testimony may be used to explain or round out the data. However, oral testimony alone is insufficient because it does not comply with the *MPIM*. *MPIM*, ch. 5, §§ 5.7 and 5.8. Additionally, this ALJ recognizes there were instances where a patient's compliance was slightly less than 75 percent, but fluctuated. This ALJ reviewed the medical record and considered the oral testimony on a case-by-case basis.

D. SPECIFIC MEDICAL NECESSITY IN THIS CASE

The medical record establishes all six requirements are present in this specific case, and therefore the Appellant is entitled to coverage in this specific case.

The first requirement is met. This Beneficiary was 69 years old on the date(s) of service.

The second requirement is met. The medical record does not include a copy of the May 2011 pathology report. (Exh. 2). The treatment notes however do indicate that the Beneficiary had a confirmed diagnosis of GBM. *Id.*

The third requirement is met. The medical record as a whole suggests this Beneficiary's past treatment regimen included a chemotherapy agent. (Exh. 2). The Beneficiary underwent an MRI of the head with intravenous gadolinium on March 7, 2013, which showed an area of enhancement of GBM around the resection site. (Exh. 2, pp. 25-29). The physician noted that the Beneficiary had progressive relapsed glioblastoma. *Id.*

The fourth requirement is met. This ALJ relied on the physician's attestation in the Letter of Medical Necessity that this Beneficiary was not a candidate for additional surgery. Exh. 2, pp. 6-8). Radiotherapy was considered but determined not to be a viable treatment option at the time. *Id.* The statement is consistent with the MRI findings. (Exh. 2, pp. 25-29).

The fifth requirement is met. The medical record documents that the Beneficiary had exhausted treatment options other than the NovoTTF-100A system. (Exh. 2). This ALJ reviewed the medical record closely and it did not indicate that the Beneficiary was using Avastin (or other treatment) concurrently with the NovoTTF-100A System. (Exh. 2). This ALJ thus finds that the medical record indicates the NovoTTF-100A System was prescribed and this Beneficiary used it as a monotherapy to treat the RGBM.

The sixth and final requirement is met. At hearing, the Appellant testified that the Beneficiary's compliance was 84% for the dates of service at issue. (Hearing testimony). While compliance is not addressed in the medical records, this ALJ finds this acceptable as this was the Beneficiary's

first month of treatment and the medical records are prior to the date of service under review. This ALJ finds the Appellant has established by a preponderance of the evidence that the coverage requirements for the NovoTTF-100A System were met.

Because the Appellant is entitled to coverage for the NovoTTF-100A System, the Appellant is also entitled to coverage for the accessories and/or supplies related to the NovoTTF-100A System. This ALJ finds the insulated transducer arrays are covered.

For the reasons indicated above, this ALJ finds the NovoTTF-100A System was medically reasonable and necessary for this Beneficiary on the date(s) of service. The insulated transducer arrays were also medically reasonable and necessary. The Appellant is entitled to coverage and reimbursement for these services under Medicare Part B.

E. OTHER ISSUES RELATED TO PAYMENT AND/OR DOCUMENTATION

The Appellant has provided valid evidence of proof of delivery of the transducer arrays. Medicare requires suppliers of durable medical equipment, like the Appellant, to deliver the item(s) of durable medical equipment to the Beneficiary and maintain proof of delivery in order to be eligible to receive payment for a Medicare-covered item. *See* 42 C.F.R. § 424.57(c)(12). The three methods of delivery include: supplier delivering directly to the beneficiary or authorized representative; supplier utilizing a delivery/shipping service to delivery items; and delivery of items to a nursing facility on behalf of the beneficiary. CMS, *Medicare Program Integrity Manual (MPIM) (Internet-Only Manual Publ'n 100-8)*, ch. 5, § 5.8 (July 2011).

In the present case, the transducer arrays were delivered directly to the Beneficiary. A proof of delivery must include: the Beneficiary's name, delivery address, a description of the items delivered, the quantity delivered, the date delivered, and the Beneficiary's signature. *See* Noridian, Jurisdiction D Supplier Manual, Chapter 3. In the present case, the Beneficiary signed and dated that he received the transducer arrays on March 18, 2013. (Exh. 2, p. 10-11). Additionally, the Novocure representative delivered the equipment and attended the treatment start on March 18, 2013. (Exh. 2, pp. 4-5). This ALJ finds that there was valid proof of delivery in the present case and that the proof of delivery contains the required information.

The Appellant prevailed on this additional issue, and on coverage in general (see previous Sections).

F. LIMITATION OF LIABILITY

There is no issue regarding liability since the services at issue were medically reasonable and necessary.

Conclusions of Law

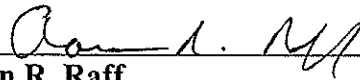
This decision is **FULLY FAVORABLE** for the Appellant. The 40 units of insulated transducer arrays (HCPCS code A9900) the Appellant billed on March 18, 2013, were medically reasonable and necessary. The Appellant is entitled to Medicare Part B coverage and payment for the DME and supplies on the respective dates of service.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated: JUL 18 2018



Aaron R. Raff
U.S. Administrative Law Judge



Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

Cleveland Field Office
200 Public Square, Suite 1300
Cleveland, OH 44114-2316
216-615-4000 (Main)
216-615-7545 (ALJ Smith Team)
216-615-6735 (Fax)
866-236-5089 (Toll Free)

November 6, 2018

[REDACTED]
[REDACTED]
OAKLAND, CA 94603-3233

NOTICE OF DECISION

Appellant: [REDACTED]
OMHA Appeal Number: 1-7732748696

Enclosed is the decision for the above case. This decision is based on the administrative record, including any evidence or testimony presented at the hearing, if one was held. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault. In addition, the decision may be reopened within 180 calendar days from the date of the decision for good cause. Good cause exists when there is new and material evidence that was not available or known at the time of the decision and may result in a different conclusion, or when the evidence that was considered clearly shows on its face that an obvious error was made at the time of the decision.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. Other parties may also appeal the decision. In addition, the Medicare Appeals Council may decide to review the decision on its own motion. If no party appeals the decision and the Medicare Appeals Council does not review the decision, the decision is binding on all parties and you and the other parties will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.

How much time do I have to file an appeal?

The Medicare Appeals Council must receive your written appeal **within 60 calendar days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 calendar days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing, except that a request for expedited review of a Part D decision may be made orally as described below. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree.

You may submit a written request for review to the Medicare Appeals Council using one of three available methods: mail, fax, or electronic filing (E-File). **Please do not submit your request for review using more than one method.** Regardless of how you file your appeal, **you must always send a copy of your written request for review to the other parties who received a copy of the decision.**

If you are filing a written request for review, you may use the enclosed *Request for Review* (form DAB-101), or you may write a letter containing the following:

- The beneficiary's/enrollee's name (and telephone number for Part D appeals);
- The beneficiary's/enrollee's Medicare number (Health Insurance Claim Number or Medicare Beneficiary Identifier);
- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's decision;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's decision (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

Filing by mail:

Mail your appeal and a copy of the enclosed decision to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Filing by fax:

Fax your appeal and a copy of the enclosed decision to (202) 565-0227.

Filing by computer:

Using your web browser, visit the Medicare Operations Division Electronic Filing System (MOD E-File) website at <https://dab.efile.hhs.gov/mod>.

To file a new appeal using MOD E-File, you will need to register by:

- (1) Clicking **Register** on the MOD E-File home page;
- (2) Entering the information requested on the "Register New Account" form; and
- (3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at <https://dab.efile.hhs.gov/mod/users/new>. You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party's representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

- (1) Logging into MOD E-File;
- (2) Clicking the **File New Appeal** menu button on the top right of the screen;
- (3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
- (4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the "File New Appeal – Medicare Operations Division" form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed decision. All documents should be submitted in Portable Document Format (PDF) whenever possible. Any document, including a Request for Review, will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.

Currently, the documents that may be filed electronically are the:

- (1) Request for Review;
- (2) Appointment of Representative form (OMB Form 0938-0950);
- (3) Copy of Administrative Law Judge or attorney adjudicator decision;
- (4) Memorandum or brief or other written statement in support of your appeal; and
- (5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D decision may be made by telephone to **(866) 365-8204**. You must provide the information listed in the bullet points above and a statement that you are requesting an expedited review within 60 calendar days after receipt of this notice of

decision. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file.

Please note that your request for review will only be expedited if (1) the appeal involves an issue specified in 42 C.F.R. § 423.566(b), but does not include solely a request for payment of a Part D drug that has already been furnished, and (2) the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at <http://www.hhs.gov/dab/>. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll free), if you have questions about filing an appeal.

cc:

DAN MCCOY
NOVOCURE
195 COMMERCE WAY
PORTSMOUTH, NH 03801

KAISER FOUNDATION HEALTH PLAN
ATTN: AUDRA GIST/JARED DYSON
1800 HARRISON ST.
6TH FLOOR
OAKLAND, CA 94612

Enclosures:

OMHA-152, Decision
DAB-101, Request for Review

REQUEST FOR REVIEW OF ADMINISTRATIVE LAW JUDGE (ALJ) MEDICARE DECISION / DISMISSAL

1. APPELLANT (the party requesting review)	2. ALJ APPEAL NUMBER (on the decision or dismissal)
3. BENEFICIARY*	4. HEALTH INSURANCE CLAIM NUMBER (HICN)*

*If the request involves multiple claims or multiple beneficiaries, attach a list of beneficiaries, HICNs, or other information to identify all claims being appealed.

5. PROVIDER, PRACTITIONER, OR SUPPLIER	6. SPECIFIC ITEM(S) OR SERVICE(S)
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7. Medicare claim type: ☐ Part A ☐ Part B ☐ Part C - Medicare Advantage
☐ Part D - Medicare Prescription Drug Plan ☐ Entitlement/enrollment for Part A or Part B

8. Does this request involve authorization for an item or service that has not yet been furnished?

☐ Yes If Yes, skip to Block 8.
☐ No If No, Specific Dates of Service:

9. If the request involves authorization for a prescription drug under Medicare Part D, would application of the standard appellate timeframe seriously jeopardize the beneficiary's life, health, or ability to regain maximum function (as documented by a physician) such that expedited review is appropriate? ☐ Yes ☐ No

I request that the Medicare Appeals Council review the ALJ's ☐ decision or ☐ dismissal order (check one) dated _____. I disagree with the ALJ's action because (specify the parts of the ALJ's decision or dismissal you disagree with and why you think the ALJ was wrong):

(Attach additional sheets if you need more space)

PLEASE ATTACH A COPY OF THE ALJ DECISION OR DISMISSAL ORDER YOU ARE APPEALING.

DATE			DATE		
APPELLANT'S SIGNATURE (the party requesting review)			REPRESENTATIVE'S SIGNATURE (include signed appointment if not already submitted.)		
PRINT NAME			PRINT NAME		
ADDRESS			ADDRESS		
CITY, STATE, ZIP CODE			CITY, STATE, ZIP CODE		
TELEPHONE NUMBER	FAX NUMBER	E-MAIL	TELEPHONE NUMBER	FAX NUMBER	E-MAIL

(SEE FURTHER INSTRUCTIONS ON PAGE 2)

If you have additional evidence, submit it with this request for review. If you need more time, you must request an extension of time in writing now, explaining why you are unable to submit the evidence or legal argument now.

If you are a provider, supplier, or a beneficiary represented by a provider or supplier, and your case was reconsidered by a Qualified Independent Contractor (QIC), the Medicare Appeals Council will not consider new evidence related to issues the QIC has already considered unless you show that you have a good reason for submitting it for the first time to the Medicare Appeals Council.

IMPORTANT: Include the HICN and ALJ Appeal Number on any letter or other material you submit.

This request must be received within 60 calendar days after you receive the ALJ's decision or dismissal, unless we extend the time limit for good cause. We assume you received the decision or dismissal 5 calendar days after it was issued, unless you show you received it later. If this request will not be received within 65 calendar days from the date on the decision or dismissal order, please explain why on a separate sheet.

You must file your request for review in writing with the Medicare Appeals Council at:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

You may send the request for review by U.S. Mail, a common carrier such as FedEx, or by fax to (202) 565-0227. If you send a fax, please do not also mail a copy. **You must send a copy of your appeal to the other parties and indicate that all parties, to include all beneficiaries, have been copied on the request for review. For claims involving multiple beneficiaries, you may submit a copy of the cover letters issued or a spreadsheet of the beneficiaries and addresses who received a copy of the request for review.**

If you have any questions about your request for review or wish to request expedited review of a claim involving authorization of your prescription drug under Medicare Part D, you may call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100. You may also visit our web site at www.hhs.gov/dab for additional information on how to file your request for review.

PRIVACY ACT STATEMENT

The collection of information on this form is authorized by the Social Security Act (section 205(a) of title II, section 702 of title VII, section 1155 of Title XI, and sections 1852(g)(5), 1869(b)(1), 1871, 1872, and 1876(c)(5)(B) of title XVIII, as appropriate). The information provided will be used to further document your claim. Information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your claim. Information you furnish on this form may be disclosed by the Department of Health and Human Services or the Social Security Administration to another person or governmental agency only with respect to programs under the Social Security Act and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services, the Social Security Administration, or other agencies.



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Cleveland Field Office
Cleveland, Ohio

Appeal of: [REDACTED]	ALJ Appeal No: 1-7732748696
Beneficiary: [REDACTED]	Medicare Part: C
HICN: *****8412A	Before: Gary D. Smith U.S. Administrative Law Judge

DECISION

After carefully considering the evidence presented in the record, a **FAVORABLE** decision is entered for [REDACTED] (hereinafter, the Appellant/Beneficiary).

Procedural History

At all times relevant, the Beneficiary was an enrollee in Kaiser Foundation HP, Inc./Kaiser, a Medicare Advantage (MA) Plan (hereinafter, the Plan).

The Beneficiary and/or his physician requested pre-approval of Optune tumor treatment field therapy (E0766), in treatment of the Beneficiary's glioblastoma. The Plan denied pre-approval upon initial determination and redetermination.

Maximus Federal Services, a Medicare Qualified Independent Contractor (QIC), issued an unfavorable reconsideration, reasoning: "This device is not a Medicare-covered item. Based on this information, we decided that Medicare rules for coverage of an Optune device have not been met."

The Office of Medicare Hearings and Appeals (OMHA) received the Beneficiary's timely-filed request for an Administrative Law Judge (ALJ) hearing. The amount in controversy satisfies the jurisdictional threshold for a hearing before an ALJ.

On October 18, 2018 the ALJ conducted a telephonic hearing. The Beneficiary was represented by Stephanie Hales, Esquire, by Julie Miles, RN, and Dan McCoy, of Novocure. The Plan was also present. All witness(es) were sworn in, and all exhibits were admitted into the record without objection.

Issue

The QIC determined that the Plan is not required to pre-approve and/or allow coverage for the tumor treatment field therapy (E0766), in treatment of the Beneficiary's glioblastoma. The Beneficiary argues that the services warrant coverage under the terms of the Plan.

The issue before the ALJ is whether the Plan is required to pre-approve and/or allow coverage for the tumor treatment field therapy (E0766), in treatment of the Beneficiary's glioblastoma.

Findings of Fact

The Beneficiary was a 70-year-old female who presented with short term memory loss in September, 2017. (Exh. 2, pgs. 12-20.) A CT found masslike thickening of the posterior corpus callosum. (*Id.*) She was determined to have presumed glioblastoma of the splenium of the corpus callosum. (*Id.*) She completed chemoradiation and temodar cycles. (*Id.*) On March 13, 2018, a MRI showed an expansile mas centered in the splenium of the corpus callosum and extending into the bilateral occipital white matter, which was compatible with her known glioblastoma. (*Id.*)

The Beneficiary's physician prescribed and requested pre-approval for coverage of Optune therapy in treatment of the Beneficiary's glioblastoma. (Exh. 2, pgs. 1-3.)

The NCCN Clinical Practice Guidelines 2016 in Oncology for "Central Nervous System Cancers," include Tumor Treatment Therapy (TTF) treatment for recurrent glioblastoma.

Pursuant to the Food and Drug Administration (FDA), "Radiation therapy and cancer drugs can allow patients to live longer than if they had no treatment. Adding Optune to temozolomide [temodar] can allow patients to live even longer than with temozolomide [temodar] alone." https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034S013d.pdf.

Pursuant to the NIH, "The Food and Drug Administration (FDA) approved TTF for recurrent glioblastoma and newly diagnosed glioblastoma in 2011 and 2015, respectively." <https://www.ncbi.nlm.nih.gov/pmc/pubmed/28841803/>.

Pursuant to the NIH, "Glioblastoma (GBM) is the most common and aggressive malignant brain tumor in adults. Current treatment options at diagnosis are multimodal and include surgical resection, radiation, and chemotherapy. Significant advances in the understanding of the molecular pathology of GBM and associated cell signaling pathways have opened opportunities for new therapies for recurrent and newly diagnosed disease. innovative treatments, such as tumor-treating fields (TTFIELDS) [Optune] and immunotherapy, give hope for enhanced survival." <https://www.ncbi.nlm.nih.gov/diseases/2401/glioblastoma>.

Pursuant to the American Association for Cancer Research, "Interim data from the first 315 patients enrolled in the trial led the U.S. [FDA] to approve the Optune medical device for newly diagnosed glioblastoma. "Now we are reporting the final results for all 695 patients enrolled on the trial, including long-term outcome. Our data firmly establish the survival benefit of

treatment with TTFields,' said Stupp. The median overall survival for patients randomly assigned TTFields and temozolomide was 21 months, compared with 16 months for those randomly assigned temozolomide alone. The two-, three-, four-, and five-year survival rates for patients who received TTFields and temozolomide were significantly improved compared with those for patients who received temozolomide alone: 43 percent versus 31 percent; 26 percent versus 16 percent; 20 percent versus 8 percent; and 13 percent versus 5 percent. TTFields showed an effect in all subgroups of patients treated, including the patients who have the most unfavorable prognostic factors." (April 2, 2017.) <https://www.aacr.org/Newsroom/Pages/News-Release-Detail.aspx?ItemID=1029>.

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) § 1869(b)(1)(A).

In implementing this statutory directive, the Secretary has delegated his authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *Id.*

A hearing before an ALJ is only available if the remaining amount in controversy meets a jurisdictional threshold. Additionally, the request for ALJ hearing must be timely filed within sixty days after receipt of the reconsideration. 42 C.F.R. § 405.1002.

B. Scope of Review

Under the Centers for Medicare and Medicaid Services' (CMS) implementation policy for the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. Law 106-554, app. F, 114 Stat. 2763, 2763A-463, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. Law 108-173, 117 Stat. 2066, all initial determinations by CMS contracted Carriers after January 1, 2006, are governed by the ALJ hearing procedures set forth at 42 C.F.R. §§ 405.1000 through 405.1054. 70 Fed. Reg. 11420, 11424-26 (Mar. 8, 2005).

"The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor....The ALJ may consider a new issue at the hearing if he or she notifies all of the parties about the new issue any time before the start of the hearing. The new issue may include issues resulting from the participation of CMS at the ALJ level of adjudication and from any evidence and position papers submitted by CMS for the first time to the ALJ. The ALJ or any party may raise a new issue;

however, the ALJ may only consider a new issue if its resolution - (i) Could have a material impact on the claim or claims that are the subject of the request for hearing; and - (ii) Is permissible under the rules governing reopening of determinations and decisions.” 42 C.F.R. § 405.1032.

“If the evidence in the hearing record supports a finding in favor of appellant(s) on every issue, the ALJ may issue a hearing decision without giving the parties prior notice and without holding a hearing. The notice of the decision informs the parties that they have the right to a hearing and a right to examine the evidence on which the decision is based.” 42 C.F.R. 405.1038

C. Standard of Review

“The [Office of Medicare Hearings and Appeals]...is staff[ed] with Administrative Law Judges who conduct ‘de novo’ hearings....” 70 Fed. Reg. 36386 (June 23, 2005). An ALJ qualified and appointed pursuant to the Administrative Procedure Act acts as an independent finder of fact in conducting a hearing pursuant to section 1869 of the Act. (*Id.*)

II. Principles of Law

A. Medicare Part C

The Medicare program is set forth in Title XVIII of the Social Security Act (the Act). Under Title II of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the Medicare Advantage (MA) program was announced as a replacement to the Medicare + Choice (M+C) managed care program. A MA Plan must provide the services currently available under Medicare Parts A and B and may provide additional services if specified in its policy.

While enrolled in a MA plan, an enrollee is entitled to and restricted by the limitations and conditions of that program with respect to Medicare coverage and reimbursement. In turn, the MA plan must make available to an enrollee, or provide reimbursement for, at least all services covered under Part A and Part B of Medicare. 42 C.F.R. § 422.101.

42 C.F.R. § 422.101 states that MA plans must pay for a medical service or item if Original Medicare would pay for it.

42 C.F.R. § 422.111 states that a MA plan must disclose to its enrollees in clear, accurate terms all cost-sharing information (such as copayments, deductibles and coinsurance).

42 C.F.R. § 422.2 states that a copayment is a fixed amount charged to an enrollee on a per-service basis. The coinsurance is a fixed percentage of the total amount paid for a health care service that can be charged to an enrollee on a per-service basis.

In this case, the Plan’s Evidence of Coverage (EOC) covers items and services in accordance with the rules of Original Medicare. (Exh. 1.)

B. Medicare Part B

Part B of Title XVIII, the Supplementary Medical Insurance program, provides coverage for a variety of medical services and supplies furnished by physicians, or by others in connection with physicians' services, for outpatient hospital services, and for a number of other specific health-related items and services. Individuals participate voluntarily in the Medicare Part B program and pay a monthly premium.

In relevant part, Section 1861(s) of the Act, identifies "medical and other health services" as including the following items or services: physicians services and diagnostic tests.

C. Local Coverage Determinations

Section 1842(a)(1)(A) of the Act gives the U.S. Secretary of the Department of Health and Human Services (hereinafter the Secretary) the authority to enter into contracts with private entities for the day-to-day operations of the Medicare program. The Administrative Law Judge is bound by the Act at 42 U.S.C. § 1395 et. seq., the Code of Federal Regulations, CMS Rulings, and National Coverage Determinations. While not binding on the Administrative Law Judge, Local Coverage Determinations, LCDs, which are issued by the contractors, are entitled to substantial deference to the extent that they are consistent with the Social Security Act and CMS regulations. See *Lyng v. Payne*, 476 U.S. 926, 939 (1986); 42 C.F.R. § 405.1062.

The Medicare contractor with jurisdiction over the Beneficiary's geographic area has issued LCD L34823, which states that Medicare excludes coverage for tumor treatment field therapy (E0766) as not medically reasonable and necessary.

Analysis

Pursuant to LVD L34823, tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. The regulations direct an ALJ to give "substantial deference" to LCDs. 42 C.F.R. § 405.1062(a). However, the regulations also permit an ALJ to decline to follow a LCD in an individual case. 42 C.F.R. § 405.1062(a). In this case, the ALJ does not give substantial deference to LCD L34823. The ALJ is not challenging the validity or substance of the LCD. The ALJ finds that, based upon the unique facts of this case, the LCD should not be followed.

Research articles, FDA approval, and NIH studies support the conclusion that TTFT (Optune) is safe and effective in treating the Beneficiary's diagnosis of glioblastoma. The NIH identifies glioblastoma as a rare disease with limited treatment options. <https://rarediseases.info.nih.gov/diseases/2401/glioblastoma>. The FDA approved TTF for recurrent glioblastoma and newly diagnosed glioblastoma in 2011 and 2015. <https://www.ncbi.nlm.nih.gov/pmc/pubmed/28841803/>. This reflects successful clinical trials in which Optune (tumor treatment field therapy (E0766)) in combination with temozolomide allowed patients to live even longer than with temozolomide alone.

The Beneficiary was a 70-year-old female who presented with short term memory loss in September, 2017. A CT found masslike thickening of the posterior corpus callosum. She was determined to have presumed glioblastoma of the splenium of the corpus callosum. She completed chemoradiation and temodar cycles. On March 13, 2018, a MRI showed an expansile mas centered in the splenium of the corpus callosum and extending into the bilateral occipital white matter, which was compatible with her known glioblastoma. The Beneficiary's physician prescribed and requested pre-approval for coverage of Optune therapy in treatment of the Beneficiary's glioblastoma.

Although a specific policy, LCD L34823 does not allow Medicare coverage for Optune, the research provided and unique facts of this case demonstrate that there are other factors to consider in this case that outweigh the application of LCD L34823. The ALJ finds that, in this case, due to the unique facts and medical research specific to this individual case, LCD L34823 should not be followed.

In this case, the Optune device (tumor treatment field therapy (E0766)) meets the requirements for Medicare coverage because the device/services have been shown to be reasonable and necessary for the treatment of glioblastoma. The FDA has approved Optune as being safe and effective for treating glioblastoma. Further, the documentation demonstrates that the use of Optune in this case, used consistent with the FDA indication, can be expected to provide a favorable outcome and higher quality of life for the Beneficiary. The ALJ finds that the tumor treatment field therapy (E0766), in treatment of the Beneficiary's glioblastoma is a covered benefit under the terms of the Plan.

Conclusions of law

Under the circumstances described in this case, tumor treatment field therapy (E0766) is a covered benefit under the terms of the Plan. The Plan is required to pre-approve and allow coverage for the tumor treatment field therapy (E0766), in treatment of the Beneficiary's glioblastoma.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim(s) in accordance with this decision.

Dated: _____

NOV 06 2018

SO ORDERED.


Gary D. Smith

U.S. Administrative Law Judge



Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

Cleveland Field Office
200 Public Square, Suite 1300
Cleveland, OH 44114-2316
216-615-4000 (Main)
216-615-7545 (ALJ Smith Team)
216-615-6735 (Fax)
866-236-5089 (Toll Free)

December 12, 2017

[REDACTED]

NOTICE OF DECISION

Appellant:

OMHA Appeal Number: I-6695659714

Enclosed is the decision for the above case. This decision is based on the administrative record, including any evidence or testimony presented at the hearing, if one was held. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault. In addition, the decision may be reopened within 180 calendar days from the date of the decision for good cause. Good cause exists when there is new and material evidence that was not available or known at the time of the decision and may result in a different conclusion, or when the evidence that was considered clearly shows on its face that an obvious error was made at the time of the decision.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. Other parties may also appeal the decision. In addition, the Medicare Appeals Council may decide to review the decision on its own motion. If no party appeals the decision and the Medicare Appeals Council does not review the decision, the decision is binding on all parties and you and the other parties will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.

How much time do I have to file an appeal?

The Medicare Appeals Council must receive your written appeal **within 60 calendar days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 calendar days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing, except that a request for expedited review of a Part D decision may be made orally as described below. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree.

You may submit a written request for review to the Medicare Appeals Council using one of three available methods: mail, fax, or electronic filing (E-File). **Please do not submit your request for review using more than one method.** Regardless of how you file your appeal, **you must always send a copy of your written request for review to the other parties who received a copy of the decision.**

If you are filing a written request for review, you may use the enclosed *Request for Review* (form DAB-101), or you may write a letter containing the following:

- The beneficiary's/enrollee's name (and telephone number for Part D appeals);
- The beneficiary's/enrollee's health insurance claim number;
- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's decision;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's decision (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

Filing by mail:

Mail your appeal and a copy of the enclosed decision to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Filing by fax:

Fax your appeal and a copy of the enclosed decision to **(202) 565-0227**.

Filing by computer:

Using your web browser, visit the Medicare Operations Division Electronic Filing System (MOD E-File) website at <https://dab.efile.hhs.gov/mod>.

To file a new appeal using MOD E-File, you will need to register by:

- (1) Clicking **Register** on the MOD E-File home page;
- (2) Entering the information requested on the "Register New Account" form; and
- (3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at <https://dab.efile.hhs.gov/mod/users/new>. You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party's representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

- (1) Logging into MOD E-File;
- (2) Clicking the **File New Appeal** menu button on the top right of the screen;
- (3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
- (4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the "File New Appeal Medicare Operations Division" form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed decision. All documents should be submitted in Portable Document Format (PDF) whenever possible. Any document, including a Request for Review, will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.

Currently, the documents that may be filed electronically are the:

- (1) Request for Review;
- (2) Appointment of Representative form (OMB Form 0938-0950);
- (3) Copy of Administrative Law Judge or attorney adjudicator decision;
- (4) Memorandum or brief or other written statement in support of your appeal; and
- (5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D decision may be made by telephone to **(866) 365-8204**. You must provide the information listed in the bullet points above and a statement that you are requesting an expedited review within 60 calendar days after receipt of this notice of

decision. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file.

Please note that your request for review will only be expedited if (1) the appeal involves an issue specified in 42 C.F.R. § 423.566(b), but does not include solely a request for payment of a Part D drug that has already been furnished, and (2) the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at <http://www.hhs.gov/dab/>. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll free), if you have questions about filing an appeal.

cc:

UPMC FOR YOU, INC
600 Grant Street
55th Floor
Pittsburgh, PA 15219

MAXIMUS
IRE PART C APPEALS-ALJ
3750 MONROE AVENUE.
SUITE 702
PITTSFORD, NY 14534-1302

Enclosures:

OMHA-152, Decision
DAB-101, Request for Review

DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS) / DEPARTMENTAL APPEALS BOARD Form DAB-101 (08/09)

REQUEST FOR REVIEW OF ADMINISTRATIVE LAW JUDGE (ALJ) MEDICARE DECISION / DISMISSAL

1. APPELLANT (the party requesting review)	2. ALJ APPEAL NUMBER (on the decision or dismissal)
3. BENEFICIARY*	4. HEALTH INSURANCE CLAIM NUMBER (HICN)*

*If the request involves multiple claims or multiple beneficiaries, attach a list of beneficiaries, HICNs, or other information to identify all claims being appealed.

5. PROVIDER, PRACTITIONER, OR SUPPLIER	6. SPECIFIC ITEM(S) OR SERVICE(S)
--	-----------------------------------

7. Medicare claim type: ☐ Part A ☐ Part B ☐ Part C - Medicare Advantage
☐ Part D - Medicare Prescription Drug Plan ☐ Entitlement/enrollment for Part A or Part B

8. Does this request involve authorization for an item or service that has not yet been furnished?

- ☐ Yes If Yes, skip to Block 8.
☐ No If No, Specific Dates of Service:

9. If the request involves authorization for a prescription drug under Medicare Part D, would application of the standard appellate timeframe seriously jeopardize the beneficiary's life, health, or ability to regain maximum function (as documented by a physician) such that expedited review is appropriate? ☐ Yes ☐ No

I request that the Medicare Appeals Council review the ALJ's ☐ decision or ☐ dismissal order [check one] dated _____. I disagree with the ALJ's action because (specify the parts of the ALJ's decision or dismissal you disagree with and why you think the ALJ was wrong):

(Attach additional sheets if you need more space)

PLEASE ATTACH A COPY OF THE ALJ DECISION OR DISMISSAL ORDER YOU ARE APPEALING.

DATE			DATE		
APPELLANT'S SIGNATURE (the party requesting review)			REPRESENTATIVE'S SIGNATURE (include signed appointment if not already submitted.)		
PRINT NAME			PRINT NAME		
ADDRESS			ADDRESS		
CITY, STATE, ZIP CODE			CITY, STATE, ZIP CODE		
TELEPHONE NUMBER	FAX NUMBER	E-MAIL	TELEPHONE NUMBER	FAX NUMBER	E-MAIL

(SEE FURTHER INSTRUCTIONS ON PAGE 2)

Form DAB-101 (08/09)

If you have additional evidence, submit it with this request for review. If you need more time, you must request an extension of time in writing now, explaining why you are unable to submit the evidence or legal argument now.

If you are a provider, supplier, or a beneficiary represented by a provider or supplier, and your case was reconsidered by a Qualified Independent Contractor (QIC), the Medicare Appeals Council will not consider new evidence related to issues the QIC has already considered unless you show that you have a good reason for submitting it for the first time to the Medicare Appeals Council.

IMPORTANT: Include the HICN and ALJ Appeal Number on any letter or other material you submit.

This request must be received within 60 calendar days after you receive the ALJ's decision or dismissal, unless we extend the time limit for good cause. We assume you received the decision or dismissal 5 calendar days after it was issued, unless you show you received it later. If this request will not be received within 65 calendar days from the date on the decision or dismissal order, please explain why on a separate sheet.

You must file your request for review in writing with the Medicare Appeals Council at:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

You may send the request for review by U.S. Mail, a common carrier such as FedEx, or by fax to (202) 565-0227. If you send a fax, please do not also mail a copy. **You must send a copy of your appeal to the other parties and indicate that all parties, to include all beneficiaries, have been copied on the request for review. For claims involving multiple beneficiaries, you may submit a copy of the cover letters issued or a spreadsheet of the beneficiaries and addresses who received a copy of the request for review.**

If you have any questions about your request for review or wish to request expedited review of a claim involving authorization of your prescription drug under Medicare Part D, you may call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100. You may also visit our web site at www.hhs.gov/dab for additional information on how to file your request for review.

PRIVACY ACT STATEMENT

The collection of information on this form is authorized by the Social Security Act (section 205(a) of title II, section 702 of title VII, section 1155 of Title XI, and sections 1852(g)(5), 1869(b)(1), 1871, 1872, and 1876(c)(5)(B) of title XVIII, as appropriate). The information provided will be used to further document your claim. Information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your claim. Information you furnish on this form may be disclosed by the Department of Health and Human Services or the Social Security Administration to another person or governmental agency only with respect to programs under the Social Security Act and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services, the Social Security Administration, or other agencies.



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Midwest Field Office
Cleveland, OH

Appeal of: [REDACTED]	ALJ Appeal No.: 1-6695659714
Beneficiary: [REDACTED]	Medicare Part C
HICN: [REDACTED]	Before: Gary D. Smith U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record and at the hearing, a **FAVORABLE** decision is entered for the Appellant.

PROCEDURAL HISTORY

On June 8, 2017 the Beneficiary/Appellant submitted a request for pre-approval of a Novocure Electrical Stimulator Device to UPMC for Life Dual ("The Plan"), provider of the Beneficiary's Medicare Advantage Plan. The request was initially denied on June 20, 2017. The Plan issued a second notice of denial on July 19, 2017. Thereafter, the Appellant requested a reconsideration by the Qualified Independent Contractor (QIC) Maximus Federal Services. Maximus issued an unfavorable determination on August 7, 2017, finding the Appellant was requesting pre-approval of Tumor Treatment Therapy (TFT) that was not medically necessary in accordance with Local Coverage Determination (LCD) Tumor Treatment Field Therapy (TTFT) (L34823).

An appeal and request for an Administrative Law Judge (ALJ) Hearing, pursuant to 42 CFR § 405.1002(a), was timely filed and received by the Office of Medicare Hearings and Appeals (OMHA) on August 25, 2017. The amount in controversy meets the jurisdictional requirements for hearing at OMHA. A telephone hearing was held on November 2, 2017 before the undersigned ALJ. The Appellant was represented by Stephanie Hales, Esq. Justin Kelly and Jorge Morales. The Plan appeared and was represented by David Miller, Esq. and Dr. Louis Piccoli. All hearing exhibits were admitted without objection.

ISSUE

The issue to be determined is: Whether the Medicare Advantage Plan should pre-approve the Appellant's request of a Novocure Electrical Device.

FINDINGS OF FACT

The Beneficiary/Appellant is a 62 year old female Medicare recipient and a member of UPMC for Life, a Medicare Advantage Plan.

The record contains progress notes with encounter dates of 12/15/16, 1/16/17, 2/20/17, 5/17/17, 5/22/17, and 5/23/17. (*Exhibit 2*).

The record contains a progress note from an encounter on 5/31/17. (*Exhibit 2*, pp. 6-11). The Beneficiary/Appellant had a diagnosis of glioblastoma multiforme. (*Id.*). The plan of care called for treatment with Avastin, Temozolomide, and Optune. (*Id.*). A MRI of the brain was to be repeated in two (2) months. (*Id.*).

The record contains a progress note from an encounter on 6/7/17. (*Id.* at 12-17). The Beneficiary/Appellant was documented as having completed six (6) cycles of temozolomide and prophylaxis. (*Id.*). The plan of care called for Avastin and Optune, along with a MRI of the brain in two (2) months. (*Id.*).

The record contains MRI of the brain results from 6/20/16, 7/29/16 and 2/13/17. (*Id.* at 31, 34). The MRI dated 2/13/17 noted there was progression of right periventricular FLAIR hyperintensity with new foci of enhancement and questionable diffusion restriction. (*Id.*). This was indicative of possible disease progression. (*Id.*).

Mr. Kelly testified at hearing. (*See*, hearing CD). Mr. Kelly provided an overview of the device at issue. (*Id.*). The device is FDA approved. (*Id.*). Most commercial insurance carriers and some Medicaid programs cover use of the device. (*Id.*). The device is used to care for primary brain tumors. (*Id.*). These tumors are typically aggressive in nature. (*Id.*). The Beneficiary/Appellant was first diagnosed in March of 2016. (*Id.*). The Beneficiary/Appellant completed chemo radiation and progress was identified in May 2017. (*Id.*). She was identified as recurrent at that point. (*Id.*). The Beneficiary/Appellant began treatment with the device on June 19, 2017. (*Id.*). The Beneficiary/Appellant's first MRI following treatment of the device was in August 2017. (*Id.*). That MRI showed the Beneficiary/Appellant had stable disease. (*Id.*). The Beneficiary/Appellant's disease has limited treatment options. (*Id.*). Allegany Health Network and other cancer centers have used Optune with excellent outcomes. (*Id.*). The device was FDA approved in 2011 for recurrent tumors. (*Id.*). In 2015 the device was approved for newly diagnosed tumors. (*Id.*). They have received twenty (20) Part C Favorable decisions and thirteen (13) positive fee for service determinations to date regarding this device. (*Id.*).

Dr. Piccoli testified at hearing. (*See*, hearing CD). The doctor stated the assignment of a HCPC code only says the item has a code. (*Id.*). There is no brain tumor were this device is the standard of care to prescribe this device for brain tumors. (*Id.*). The LCD views this device as

not reasonable and necessary. (*Id.*). This device is an option for treatment of this form of brain cancer, but not a requirement. (*Id.*).

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

An individual or organization that is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) §1869(b)(1)(A).

In implementing this statutory directive, the Secretary has delegated his authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *Id.*

A hearing before an ALJ is only available if the remaining amount in controversy meets the minimum requirement. 42 C.F.R. §405.1006. The request for hearing is timely if filed within sixty (60) days after receipt of a QIC reconsideration decision. *See* 42 C.F.R. § 405.1014.

B. Scope of Review

Under the Centers for Medicare and Medicaid Services' (CMS) implementation policy for the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. Law 106-554, app. F, 114 Stat. 2763, 2763A-463, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. Law 108-173, 117 Stat. 2066, all Medicare Part A and Part B claims, which have been issued a redetermination by a Fiscal Intermediary (FI) on or after May 1, 2005, and all Medicare Part B claims, which have been issued a redetermination by a Carrier on or after January 1, 2006, are governed by the ALJ hearing procedures outlined at 42 C.F.R. § 405.1000 through § 405.1054. *See* 70 Fed. Reg. 11420, 11424-26 (Mar. 8, 2005).

"The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. (For purposes of this provision, the term "party" does not include a representative of CMS or one of its contractors that may be participating in the hearing.) However, if evidence presented before the hearing causes the ALJ to question a favorable portion of the determination, he or she notifies the parties before the hearing and may consider it an issue at the hearing." 42 C.F.R. § 405.1032(a).

"An ALJ may also issue a decision on the record on his or her own initiative if the evidence in the hearing record supports a fully favorable finding." 42 C.F.R. § 405.1000(g). In addition, "[i]f

all parties to the hearing waive their right to appear at the hearing in person or by telephone or video-conference, the ALJ may make a decision based on the evidence that is in the file and any new evidence that is submitted for consideration.” 42 C.F.R. § 405.1000(e).

C. Standard of Review

“The ALJ conducts a de novo review and issues a decision based on the hearing record.” (42 C.F.R. § 405.1000(f)).

II. Principles of Law

A. Statutes and Regulations

The Medicare Part C program entitles a beneficiary to have Medicare services paid for by Medicare Advantage Organizations through Medicare Advantage Plans. 42 C.F.R. § 422.1(b). As a requirement for the plans, the Code of Federal Regulations observes that Medicare Advantage plans must pay for medical services if Medicare Part A or B would reimburse for it. 42 CFR § 422.101. Medicare also allows an MA plan to specify the network of providers from which enrollee’s may obtain services. 42 CFR §422.112(a). In addition as to out-of-network visits, the CFR states health plans are not required to pay for local unauthorized care unless it is a medical emergency. 42 CFR §422.113. These emergency services must be the result of an unforeseen illness or injury and it was not reasonable for the enrollee to receive services from a plan physician. *Id.*

Section 1833(e) of the Act states that “[n]o payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.”

B. Policy and Guidance

“The primary authority for all coverage provisions and subsequent policies is the Social Security Act (the Act). Contractors use Medicare policies in the form of regulations, NCDs [*national coverage determinations*], coverage provisions in interpretive manuals, and LCDs [*local coverage determinations*] to apply the provisions of the Act.” Medicare Program Integrity Manual (MPIM) (Internet-Only Manual Publ’n 100-08) ch. 13, § 13.1 (May 2004). Section 1871(a)(2) of the Act provides that unless promulgated as a regulation by The Centers for Medicare and Medicaid Services (CMS), no rule, requirement, or statement of policy, other than a National Coverage Determination (NCD), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. *See also* 42 C.F.R. § 405.1060. The CMS administers the Medicare Program (Act §§ 1102, 1871, and 1874) and contracts with carriers and intermediaries (Medicare contractors) to act on its behalf in determining and making payments to providers and suppliers of Medicare items and services. Act §§ 1816 and 1842.

In lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local medical review policies (LMRPs) or local coverage determinations (LCDs). Medicare contractors issue written determinations, called LCDs, specifying under what clinical circumstances a service is considered to be reasonable and necessary. They are administrative and educational tools to assist providers in submitting correct claims for payment. MPIM, *Id.*, § 13.1.3. Contractors publish LCDs to provide guidance to the public and medical community within their jurisdictions whether, on a contractor-wide basis, a particular item or service is covered. Act, § 1869(i)(2)(B). LCDs are used only on a contractor-wide basis and may differ between contractors in different regions of the country.

An ALJ is not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. *See* 42 C.F.R. § 405.1062(a). If an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed. *See* 42 C.F.R. § 405.1062(b).

For the period of time relevant to this case, Noridian Healthcare Solutions, LLC issued an LCD for Tumor Treatment Field Therapy (L34823) (hereinafter LCD L34823) which sets forth the limitations of coverage and/or medical necessity for Tumor Treatment Field Therapy (TTFT). The LCD states:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.

- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

GENERAL

A Detailed Written Order (DWO) (if applicable) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed DWO, the claim shall be denied as not reasonable and necessary.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.

ANALYSIS

Maximus issued an unfavorable determination, finding the Appellant was requesting pre-approval of Tumor Treatment Therapy (TTFT) that was not medically necessary in accordance with Local Coverage Determination (LCD) Tumor Treatment Field Therapy (TTFT) (L34823). The undersigned finds the testimony and record support a deviation from the LCD in this particular case.

The device at issue received FDA approval through the pre-market approval process in April 2011. This approval process is considered to be the most rigorous. The device was deemed to not be experimental or investigational. In 2011, the FDA approved the device for recurrent tumors. This was followed by FDA approval for initial tumors in 2015.

There are approximately 600 oncology centers in the United States that are certified to use this device. The certification process includes training in identifying appropriate patients for this modality.

The Appellant's representative indicated that had received twenty (20) favorable alternative decisions notwithstanding the LCD. Additionally, the Plan's physician acknowledged this is a recognized treatment option, and the Plan is considering changing its coverage option.

The undersigned has given substantial deference to the LCD. However, the record and testimony has provided significant evidence to overcome the substantial deference to the LCD. This applies to the facts and circumstances as present in this particular case. Here, the Beneficiary was diagnosed with glioblastoma multiforme. The Beneficiary underwent alternative treatment therapies. Despite undergoing therapy, the Beneficiary was identified as being recurrent. It was only after undergoing prior therapy that the Beneficiary was to undergo this type of therapy. This form of therapy has received FDA approval. The Beneficiary has limited treatment options available. Additionally, this recommended course of therapy was made by medical specialists in the radiology/oncology department at the University of Pittsburgh Medical Center, a respected cancer treatment institution. In their totality, these facts and circumstances provide substantial evidence to overcome the substantial deference afforded to the LCD.

CONCLUSIONS OF LAW

The undersigned concludes the denial of pre-approval of Novocure Electrical Device was contrary, in this particular instance, to applicable Medicare laws and regulations.

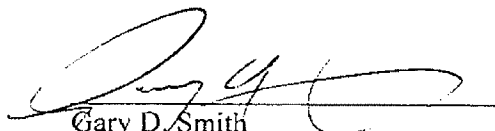
ORDER

The Medicare Contractor is directed to process the claim in accordance with this decision.

DEC 12 2017

Date

SO ORDERED.



Gary D. Smith
U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Western Field Office
Irvine, California

Appeal of: Novocure, Inc.	ALJ Appeal No. 1-2466713441
Beneficiary:	Medicare Part: B
HICN: XXX-XX-4257A	Before: Troy Smith U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, a **FULLY FAVORABLE** decision is entered for Novocure, Inc. ("Appellant").

PROCEDURAL HISTORY

The Appellant submitted a claim to Medicare for reimbursement for Novo TFF-100 System (E1399) provided to ("Beneficiary") on June 23, 2013. The initial determination denied the claims. The Appellant appealed, and at redetermination, National Government Services, the Medicare-contracted contractor ("Contractor"), issued an unfavorable decision, reasoning that the medical records submitted did not meet coverage criteria for coverage set by Medicare guidelines. (Exh. 1).

The Appellant sent its request for reconsideration to C2C Solutions, Inc., a Qualified Independent Contractor ("QIC"). On January 17, 2014, the QIC affirmed the decision of the Contractor, reasoning that the medical record submitted does not support the medical necessity of the item in question. (*Id.*).

The Appellant's request for an Administrative Law Judge ("ALJ") hearing was timely received by the Office of Medicare Hearings and Appeals ("OMHA") on February 6, 2014. (Exh. 3). The remaining amount in controversy meets the jurisdictional requirements for a hearing before the Office of Medicare Hearings and Appeals (hereinafter "OMHA"). (See 42 C.F.R. Section 405.1006).

Due notice was provided and a telephonic hearing was held on March 1, 2018, at the OMHA in Irvine, California. (Exh. 4). Stephanie Hale, Esq., appeared at the hearing on behalf of the Appellant and Justin Kelly, RN and Senior Director for Health Policy testified for the Appellant. (See Hearing CD). The Contractor submitted position papers. (Exh. 5). All the Exhibits on the List of Exhibits were admitted into evidence without objection and considered in reaching the decision herein.

ISSUES

- 1) Whether payment can be made under Part B of the Medicare program for Novo TTF-100 System (E1399) provided to the Beneficiary on June 23, 2013, i.e. whether the item was medically reasonable and necessary pursuant to the provisions of Section 1862(a)(1) of the Social Security Act and 42 C.F.R. § 411.15(k).
- 2) Whether payment can otherwise be made to the Appellant pursuant to the waiver of liability provisions under Section 1879 of the Act and 42 C.F.R. § 411.406, if it is determined that the item was not medically reasonable and necessary under Section 1862(a)(1) of the Act.

FINDINGS OF FACT

The record establishes the following facts by a preponderance of the evidence:

At the time of the date of service at issue, the Beneficiary, a 67 year-old woman, was diagnosed with recurrent glioblastoma multiforme (GBM). (Exh. 3, p. 14). She initially presented with aphasic/motor seizures in September 2011 resulting in a subtotal resection. (*Id.*). In October 2011, there was worsening of her aphasia and right hemiparesis leading to repeat craniotomy for posterior frontal tumor growth in late October 2011. (*Id.*). She then completed 42 days of radiotherapy concurrent with Temozolomide. (*Id.*). An MRI in February 2012 showed progression. (*Id.*). She began to receive 23 treatments of bevacizumab from January 19, 2012 to January 2, 2013. (*Id.* at 15). An MRI on January 16, 2013 revealed progression still. (*Id.*). Procarbazine and CCNU were added to her chemotherapy regimen. (*Id.*). Another MRI on April 17, 2013 showed further progression. (*Id.*). A re-resection was then performed on May 1, 2013 with worsening in bradyphasic language disorder and right hemiparesis following it. (*Id.*). She continued to suffer from tremors, insomnia, and seizures secondary to her GBM, as well as challenges with communication and paralysis of one side of the body. (*Id.*). Given the aggressive nature and extremely limited treatment options of her disease, her treating physician, Benjamin Lawler, M.D., recommended she receive coverage for the Novo TTF-100 System (TTF), as it was the best FDA approved option at the time for treating her recurrent GBM. (*Id.*).

According to Dr. Lawler, GMB is considered an orphan disease with extremely limited treatment options. (*Id.* at 16). The Beneficiary was either not eligible or had exhausted essentially all other FDA-approved treatments that could have benefited her. (*Id.*). TTF therapy is the only FDA-approved treatment she had not received and in his professional opinion, is the most promising treatment option for her at the present time. (*Id.*).

The Novo TTF-100A is a novel approach to cancer treatment, using alternating electrical fields to interfere with the division of malignant cells. As opposed to the treatment modalities of surgery, radiation and chemotherapy, which are all used to treat all types of cancer, alternating electrical fields have been studied in the treatment of GBM. TTF therapy is a locally or regionally delivered treatment that uses electric fields within the human body that are inferred to disrupt the rapid cell division exhibited by cancer cells. (*Id.*).

According to recently released results of a large clinical trial of patients with recurrent GBM, treatment with the Novo TTF-100 System had minimal toxicity, and long-term treatment provided feasible. TTF as a single modality showed a higher response rate and longer time to treatment failure compared to best available chemotherapy. (*Id.* at 18-19).

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) issued an approval order on April 8, 2011. The FDA Advisory Committee found data supporting the safety and effectiveness of Novo TTF-100 System for patients with GM tumors that recur after maximal surgical and radiation treatments. There is reasonable assurance that the benefits of the Novo TTF-100 System outweigh its risks when administered as a monotherapy in place of standard medical therapy with minimal or no side effects. (*Id.* at 15-16).

Justin Kelly, RN and Senior Director for Health Policy for Novocure testified that the TTF therapy is FDA approved and is a widely accepted treatment therapy by oncology centers for glioblastoma. The medical literature supports the medical necessity for the TTF.

The Medicare Contractor, CGS, submitted a position paper acknowledging that the Novocure TTF system is a durable medical equipment (DME) with the definition of Medicare rules and the Social Security Act.

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction:

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. (§ 1869(b)(1)(A) of the Act).

In implementing this statutory directive, the Secretary has delegated this authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. (*See* 70 Fed. Reg. 36386, 36387 (June 23, 2005)). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. (*Id.*)

A hearing before an ALJ is only available if the remaining amount in controversy is one hundred forty dollars (\$140) or more. (*See* 77 Fed. Reg. 59618 (September 28, 2012)). The request for hearing is timely if filed within sixty (60) days after receipt of a QIC reconsideration decision. (*See* 42 C.F.R. § 405.1014).

B. Scope of Review

Under the Centers for Medicare and Medicaid Services' (CMS) implementation policy for the Medicare, Medicaid, SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. Law 106-554, app. F, 114 Stat. 2763, 2763A-463, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. Law 108-173, 117 Stat. 2066, when considering Medicare appeals, all initial determinations by CMS contractors, subsequent to January 1, 2006 and all appeals that were subject to a QIC reconsideration, are governed by the ALJ hearing procedures set forth at 42 C.F.R. §§ 405.1000 through 405.1064. (*See* 70 Fed. Reg. 11420, 11424-26 (Mar. 8, 2005)).

The issues before the ALJ include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in the Appellant's favor. However, if evidence presented before or during the hearing causes the ALJ to question a fully favorable decision he or she will notify the Appellant and will consider it an issue at the hearing. (42 C.F.R. § 405.1032).

Title 42 of the Code of Federal Regulations Section 405.1038 permits the ALJ to decide a case on the record and not conduct an oral hearing if all the parties indicate in writing that they do not wish to appear before the Administrative Law Judge at an oral hearing. The decision of the ALJ must refer to the evidence in the record on which the decision was made.

C. Standard of Review

"The ALJ conducts a de novo review of each claim at issue. *See* 70 Fed. Reg. 36386 (June 23, 2005). A de novo review means the ALJ reviews the evidence without regard to the findings in the prior determinations on the claim and makes an independent assessment based on the evidence and the controlling laws. However, the burden of proving each element of a Medicare claim lies with the Appellant and is satisfied by submitting sufficient evidence in accordance with Medicare rules. *See e.g.*, Sections 1814(a)(1), 1815(b), and 1833(e) of the Act; *see also* 42 C.F.R. § 424.5(a)(6), 42 C.F.R. §§ 405.1018, .1028, .1030.

An Appellant may offer new evidence for the first time at the ALJ level of appeal only upon a showing of good cause why the evidence was not submitted to the QIC or a prior decision maker. The ALJ will determine whether good cause exists for the late submission of the new evidence and may only consider the evidence in making a decision if good cause is found. *See* 42 C.F.R. § 405.1018. The ALJ will determine whether good cause exists for the late submission of the new evidence and may only consider the evidence in making a decision if good cause is found. *See* 42 C.F.R. § 405.1018. *See also* 42 C.F.R. §§ 405.1028 and 405.1030. This late evidence restriction does not apply to unrepresented beneficiaries.

II. Principles of Law

A. Statutes and Regulations

Title XVIII of the Social Security Act, as amended (42 U.S.C. § 1395 *et seq.*), The Medicare Act (the Act), establishes a federally subsidized health insurance program to be administered by

the Department of Health and Human Services (HHS). Part A of the Act provides insurance for the cost of hospital and related post-hospital services. (42 U.S.C. § 1395c *et seq.*). Part B establishes a voluntary program of supplemental medical insurance covering physicians' charges and other medical services. (*See* 42 U.S.C. §§ 1395j, 1395k, and 1395x(s); 42 CFR § 410(40)(a)(2).)

Section 1862(a)(1) of the Act provides that no payment may be made under Medicare Part A or Part B for any expenses incurred for items or services which "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." (42 U.S.C. § 1395y (a)(1)(A), 42 CFR 411.15(k)(1).).

Section 1833(e) of the Act and CMS Regulations provide that claims for payment must be supported by sufficient information and documentation (42 CFR 424.5(a)(6)). Section 1833(e) of the Act states that "[n]o payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period." (42 U.S.C. § 1395l(e)).

Section 1879 of the Act provides that when Medicare coverage and payment is excluded pursuant to Section 1862(a)(1) of the Act, payment may nevertheless be made for items or services, if neither the beneficiary nor the provider or supplier knew, and could not reasonably be expected to have known, that the items or services would not be covered or payable by Medicare. CMS Regulations provide that a provider or supplier will be considered to have known that items or services would not be covered or payable by Medicare if they are given direct notice of this by CMS or any of its agents, including intermediaries and carriers, by utilization review committees, or by the beneficiary's attending physician (42 CFR 411.406(b) and (c)). A provider or supplier is also considered to have notice that services are not covered if they inform the beneficiary that the services are not covered by Medicare (42 CFR 411.406(d)). A provider or supplier is also considered to have notice that services are not covered if it is clear that they could have been expected to know that from their receipt of notices from CMS or its agents, publication in the Federal Register, or based on their "knowledge of what are considered acceptable standards of practice by the local medical community" (42 CFR 411.406(e)).

B. Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than an National Coverage Determination (NCD), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. *See also* 42 C.F.R. § 405.860. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local medical review policies ("LMRPs") or local coverage determinations ("LCDs").

According to CMS Publication 100-08 (Medicare Program Integrity Manual), Chapter 13:

13.5.1 - Reasonable and Necessary Provisions in LCDs

An item or service may be covered by a contractor LCD if:

- It is reasonable and necessary under 1862(a)(1)(A) of The Act. Only reasonable and necessary provisions are considered part of the LCD.

Reasonable and Necessary

Contractors shall describe in the draft LCD the circumstances under which the item or service is reasonable and necessary under 1862(a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member
 - Furnished in a setting appropriate to the patient's medical needs and condition;
 - Ordered and furnished by qualified personnel;
 - One that meets, but does not exceed, the patient's medical need; and
 - At least as beneficial as an existing and available medically appropriate alternative.

ANALYSIS

The primary issue on appeal is whether payment can be made under Title XVIII of the Act for the Novo TFF-100 System (E1399) provided by the Appellant to the Beneficiary on June 23, 2013, i.e. was the item medically reasonable and necessary pursuant to the provisions of Section 1862(a)(1) of the Social Security Act and 42 C.F.R. § 411.15(k).

According to Section 1862(a)(1)(A) of the Act, Medicare covers services that are medically reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member.

Since there is no NCD or LCD, the undersigned ALJ will apply provisions of Section 1862(a)(1)(A) of the Act to determine whether the Novo TFF-100 System (E1399) is medically reasonable and necessary for the Beneficiary's treatment.

The QIC issued an unfavorable decision for the Appellant, reasoning that the medical record submitted does not support the medical necessity of the item in question.

Based upon the information contained in the medical records, the undersigned ALJ disagrees with the QIC and in accordance with Medicare rules and based upon the information contained in the medical records and medical literature, the undersigned ALJ finds that the Appellant has provided sufficient documentation to support that the Novo TFF-100 System is medically reasonable and necessary for the treatment of Beneficiary's condition.

The Beneficiary, a 67 year-old woman, was diagnosed with recurrent glioblastoma multiforme (GBM). She initially presented with aphasic/motor seizures in September 2011 resulting in a subtotal resection. In October 2011, there was worsening of her aphasia and right hemiparesis leading to repeat craniotomy for posterior frontal tumor growth in late October 2011. She then completed 42 days of radiotherapy concurrent with Temozolomide. An MRI in February 2012 showed progression. She began to receive 23 treatments of bevacizumab from January 19, 2012 to January 2, 2013. An MRI on January 16, 2013 revealed progression still. Procarbazine and CCNU were added to her chemotherapy regimen. Another MRI on April 17, 2013 showed further progression. A re-resection was then performed on May 1, 2013 with worsening in bradyphasic language disorder and right hemiparesis following it. She continued to suffer from tremors, insomnia, and seizures secondary to her GBM, as well as challenges with communication and paralysis of one side of the body. Given the aggressive nature and extremely limited treatment options of her disease, her treating physician, Benjamin Lawler, M.D., recommended she receive coverage for the Novo TTF-100 System, as it was the best FDA approved option at the time for treating her recurrent GBM.

The Novo TTF-100A is a novel approach to cancer treatment, using alternating electrical fields to interfere with the division of malignant cells. As opposed to the treatment modalities of surgery, radiation and chemotherapy, which are all used to treat all types of cancer, alternating electrical fields have been studied in the treatment of GBM. TTF therapy is a locally or regionally delivered treatment that uses electric fields within the human body that are inferred to disrupt the rapid cell division exhibited by cancer cells.

According to recently released results of a large clinical trial of patients with recurrent GBM, treatment with the Novo TTF-100 System had minimal toxicity, and long-term treatment provided feasible. TTF as a single modality showed a higher response rate and longer time to treatment failure compared to best available chemotherapy.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) issued an approval order on April 8, 2011. The FDA Advisory Committee found data supporting the safety and effectiveness of Novo TTF-100 System for patients with GM tumors that recur after maximal surgical and radiation treatments. There is reasonable assurance that the benefits of the Novo TTF-100 System outweigh its risks when administered as a monotherapy in place of standard medical therapy with minimal or no side effects.

Justin Kelly, RN and Senior Director for Health Policy for Novocure testified that the TTF therapy is FDA approved and is a widely accepted treatment therapy by oncology centers for glioblastoma. The medical literature supports the medical necessity for the TTF.

The Medicare Contractor, CGS, submitted a position paper acknowledging that the Novocure TTF system is a durable medical equipment (DME) with the definition of Medicare rules and the Social Security Act.

According to Dr. Lawler, GMB is considered an orphan disease with extremely limited treatment options. The Beneficiary was either not eligible or had exhausted essentially all other FDA-approved treatments that could have benefited her. TTF therapy is the only FDA-approved treatment she had not received and in his professional opinion, is the most promising treatment

option for her at the present time. Therefore, the undersigned ALJ concludes that the Novo TTF-100 System is medically reasonable and necessary for the treatment of Beneficiary's condition and the Appellant is entitled to Medicare reimbursement for the Novo TTF-100 System (E1399) provided to the Beneficiary on June 23, 2013.

CONCLUSIONS OF LAW


1. Based on applicable laws, regulations and CMS guidance, there was sufficient information and medical documentation provided by the Appellant to show that the Novo TTF-100 System (E1399) provided to the Beneficiary on June 23, 2013 was medically reasonable and necessary pursuant to Sections 1862(a)(1)(A) of the Social Security Act.
2. Since this is a fully favorable decision, the discussion of Section 1879 of the Social Security Act is moot.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim(s) in accordance with this decision.

SO ORDERED

Dated: **MAY 3 1 2018**



Troy Smith
U.S. Administrative Law Judge



**Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Cleveland Field Office
Cleveland, Ohio**

Appeal of:	ALJ Appeal No: 1-7707765284
Beneficiary:	Medicare Part: C
HICN: *****1896A	Before: Gary D. Smith U.S. Administrative Law Judge

DECISION

After carefully considering the evidence presented in the record, a **FAVORABLE** decision is entered for . (hereinafter, the Appellant/Beneficiary).

Procedural History

At all times relevant, the Beneficiary was an enrollee in ARCADIAN Health Plan, Inc./Humana, a Medicare Advantage (MA) Plan (hereinafter, the Plan).

The Beneficiary and/or his physician requested pre-approval of tumor treatment field therapy (E0766), in treatment of the Beneficiary's glioblastoma, stage 4. The Plan denied pre-approval upon initial determination (June 4, 2018) and redetermination.

Maximus Federal Services, a Medicare Qualified Independent Contractor (QIC), issued an unfavorable reconsideration, reasoning: "Medicare specifically excludes coverage for tumor treatment field therapy (E0766) as not medically reasonable and necessary."

The Office of Medicare Hearings and Appeals (OMHA) received the Beneficiary's timely-filed request for an Administrative Law Judge (ALJ) hearing. The amount in controversy satisfies the jurisdictional threshold for a hearing before an ALJ.

On September 19, 2018,, the ALJ conducted a telephonic hearing. The Beneficiary was represented by Stephanie Hales, Esquire (Ms. Hales). Dan McCoy (Mr. McCoy) and Julie Miles (Ms. Miles), of Novacure, were also present on behalf of the Beneficiary. The Plan was not present. The witness(es) were sworn in. All exhibits were admitted into the record without objection. At the close of the hearing, the ALJ kept the record open for seven days to allow the Beneficiary to submit ALJ decisions in support of his position. These documents were received on September 26, 2018, marked as Exhibit 4, and admitted into the record without objection.

Issue

The QIC determined that the Plan is not required to pre-approve and/or allow coverage for the tumor treatment field therapy (E0766), in treatment of the Beneficiary's glioblastoma, stage 4. The Beneficiary argues that the services warrant coverage under the terms of the Plan.

The issue before the ALJ is whether the Plan is required to pre-approve and/or allow coverage for the tumor treatment field therapy (E0766), in treatment of the Beneficiary's glioblastoma, stage 4.

Findings of Fact

The Beneficiary was a 67-year-old male with a history of grade IV astrocytoma in the right frontal lobe with secondary left-sided weakness. (Exh. 2, pgs. 1-6.) This was found on February 28, 2018, status post craniotomy with maximum safe resection and carmustine wafer placement. The disease was not fully resectable. Pathology documents this as a right temporal mass/glioblastoma, grade 4. (Exh 2, pgs. 12-13.)

In the following months, he was treated with temazolamide and radiation therapy. (Exh. 2, pgs. 1-11.) In June, 2018, he started Optune therapy (alternating electrical field therapy) and was tolerating this well. A MRI of the brain showed a possible concern for early progression, but it was noted this could be a recent therapy effect. (*Id.*)

The appeal requests pre-approval for Optune therapy (E0766) , known as tumor treatment field therapy or electrical field therapy.

The NCCN Clinical Practice Guidelines 2016 in Oncology for "Central Nervous System Cancers," include Tumor Treatment Therapy (TTF) treatment for recurrent glioblastoma.

Pursuant to the Food and Drug Administration (FDA), "Radiation therapy and cancer drugs can allow patients to live longer than if they had no treatment. Adding Optune to temozolomide can allow patients to live even longer than with temozolomide alone." https://www.accessdata.fda.gov/cdrh_docs/pdf10/P1000348013d.pdf.

Pursuant to the NIH, "The Food and Drug Administration (FDA) approved TTF for recurrent glioblastoma and newly diagnosed glioblastoma in 2011 and 2015, respectively." <https://www.ncbi.nlm.nih.gov/pubmed/28841803>.

Pursuant to the NIH, "Glioblastoma (GBM) is the most common and aggressive malignant brain tumor in adults. Current treatment options at diagnosis are multimodal and include surgical resection, radiation, and chemotherapy. Significant advances in the understanding of the molecular pathology of GBM and associated cell signaling pathways have opened opportunities for new therapies for recurrent and newly diagnosed disease. innovative treatments, such as tumor-treating fields (TTFields) [Optune] and immunotherapy, give hope for enhanced survival." <https://www.ncbi.nlm.nih.gov/diseases/2491-glioblastoma>.

Pursuant to the American Association for Cancer Research, "Interim data from the first 315 patients enrolled in the trial led the U.S. [FDA] to approve the Optune medical device for newly diagnosed glioblastoma. "Now we are reporting the final results for all 695 patients enrolled on the trial, including long-term outcome. Our data firmly establish the survival benefit of treatment with TTFields," said Stupp. The median overall survival for patients randomly assigned TTFields and temozolomide was 21 months, compared with 16 months for those randomly assigned temozolomide alone. The two-, three-, four-, and five-year survival rates for patients who received TTFields and temozolomide were significantly improved compared with those for patients who received temozolomide alone: 43 percent versus 31 percent; 26 percent versus 16 percent; 20 percent versus 8 percent; and 13 percent versus 5 percent. TTFields showed an effect in all subgroups of patients treated, including the patients who have the most unfavorable prognostic factors." (April 2, 2017.) <https://www.aacr.org/Newsroom/Pages/News-Release-Detail.aspx?ItemID=1029>.

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) § 1869(b)(1)(A).

In implementing this statutory directive, the Secretary has delegated his authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *Id.*

A hearing before an ALJ is only available if the remaining amount in controversy meets a jurisdictional threshold. Additionally, the request for ALJ hearing must be timely filed within sixty days after receipt of the reconsideration. 42 C.F.R. § 405.1002.

B. Scope of Review

Under the Centers for Medicare and Medicaid Services' (CMS) implementation policy for the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. Law 106-554, app. F, 114 Stat. 2763, 2763A-463, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. Law 108-173, 117 Stat. 2066, all initial determinations by CMS contracted Carriers after January 1, 2006, are governed by the ALJ hearing procedures set forth at 42 C.F.R. §§ 405.1000 through 405.1054. 70 Fed. Reg. 11420, 11424-26 (Mar. 8, 2005).

"The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor....The ALJ

may consider a new issue at the hearing if he or she notifies all of the parties about the new issue any time before the start of the hearing. The new issue may include issues resulting from the participation of CMS at the ALJ level of adjudication and from any evidence and position papers submitted by CMS for the first time to the ALJ. The ALJ or any party may raise a new issue; however, the ALJ may only consider a new issue if its resolution - (i) Could have a material impact on the claim or claims that are the subject of the request for hearing; and - (ii) Is permissible under the rules governing reopening of determinations and decisions." 42 C.F.R. § 405.1032.

"If the evidence in the hearing record supports a finding in favor of appellant(s) on every issue, the ALJ may issue a hearing decision without giving the parties prior notice and without holding a hearing. The notice of the decision informs the parties that they have the right to a hearing and a right to examine the evidence on which the decision is based." 42 C.F.R. 405.1038

C. Standard of Review

"The [Office of Medicare Hearings and Appeals]...is staff[ed] with Administrative Law Judges who conduct 'de novo' hearings...." 70 Fed. Reg. 36386 (June 23, 2005). An ALJ qualified and appointed pursuant to the Administrative Procedure Act acts as an independent finder of fact in conducting a hearing pursuant to section 1869 of the Act. (*Id.*)

II. Principles of Law

A. Medicare Part C

The Medicare program is set forth in Title XVIII of the Social Security Act (the Act). Under Title II of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the Medicare Advantage (MA) program was announced as a replacement to the Medicare - Choice (M+C) managed care program. A MA Plan must provide the services currently available under Medicare Parts A and B and may provide additional services if specified in its policy.

While enrolled in a MA plan, an enrollee is entitled to and restricted by the limitations and conditions of that program with respect to Medicare coverage and reimbursement. In turn, the MA plan must make available to an enrollee, or provide reimbursement for, at least all services covered under Part A and Part B of Medicare. 42 C.F.R. § 422.101.

42 C.F.R. § 422.101 states that MA plans must pay for a medical service or item if Original Medicare would pay for it.

42 C.F.R. § 422.111 states that a MA plan must disclose to its enrollees in clear, accurate terms all cost-sharing information (such as copayments, deductibles and coinsurance).

42 C.F.R. § 422.2 states that a copayment is a fixed amount charged to an enrollee on a per-service basis. The coinsurance is a fixed percentage of the total amount paid for a health care service that can be charged to an enrollee on a per-service basis.

In this case, the Plan's Evidence of Coverage (EOC) covers items and services in accordance with the rules of Original Medicare. (Exh. 1.)

B. Medicare Part B

Part B of Title XVIII, the Supplementary Medical Insurance program, provides coverage for a variety of medical services and supplies furnished by physicians, or by others in connection with physicians' services, for outpatient hospital services, and for a number of other specific health-related items and services. Individuals participate voluntarily in the Medicare Part B program and pay a monthly premium.

In relevant part, Section 1861(s) of the Act, identifies "medical and other health services" as including the following items or services: physicians services and diagnostic tests.

C. Local Coverage Determinations

Section 1842(a)(1)(A) of the Act gives the U.S. Secretary of the Department of Health and Human Services (hereinafter the Secretary) the authority to enter into contracts with private entities for the day-to-day operations of the Medicare program. The Administrative Law Judge is bound by the Act at 42 U.S.C. § 1395 et. seq., the Code of Federal Regulations, CMS Rulings, and National Coverage Determinations. While not binding on the Administrative Law Judge, Local Coverage Determinations, LCDs, which are issued by the contractors, are entitled to substantial deference to the extent that they are consistent with the Social Security Act and CMS regulations. See *Lyng v. Payne*, 476 U.S. 926, 939 (1986); 42 C.F.R. § 405.1062.

The Medicare contractor with jurisdiction over the Beneficiary's geographic area has issued LCD L34823, which states that Medicare excludes coverage for tumor treatment field therapy (E0766) as not medically reasonable and necessary.

Analysis

Pursuant to LCD L34823, tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. The regulations direct an ALJ to give "substantial deference" to LCDs. 42 C.F.R. § 405.1062(a). However, the regulations also permit an ALJ to decline to follow a LCD in an individual case. 42 C.F.R. § 405.1062(a). In this case, the ALJ does not give substantial deference to LCD L34823. The ALJ is not challenging the validity or substance of the LCD. The ALJ finds that, based upon the unique facts of this case, the LCD should not be followed.

Research articles, FDA approval, and NIH studies support the conclusion that TTFT (Optune) is safe and effective in treating the Beneficiary's diagnosis of glioblastoma. The NIH identifies glioblastoma as a rare disease with limited treatment options. <https://rarediseases.info.nih.gov/diseases/2491/glioblastoma>. The FDA approved TTF for recurrent glioblastoma and newly diagnosed glioblastoma in 2011 and 2015. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC28841803/>. This reflects successful clinical trials in

which Optune (tumor treatment field therapy (E0766)) in combination with temozolomide allowed patients to live even longer than with temozolomide alone.

The Beneficiary was a 67-year-old male with a history of grade IV astrocytoma in the right frontal lobe with secondary left-sided weakness. On February 28, 2018, he underwent craniotomy with maximum safe resection and carmustine wafer placement. The disease was not fully resectable. Pathology documents his tumor as a right temporal mass/glioblastoma, grade 4. He received radiation treatment with concurrent temozolomide. Due to the nature of his disease, limited treatment options, and favorable outcomes with TTFT, Optune (tumor treatment field therapy (E0766)) is the best FDA approved option for treating his glioblastoma.

Although a specific policy, LCD L34823 does not allow Medicare coverage for Optune, the research provided and unique facts of this case demonstrate that there are other factors to consider in this case that outweigh the application of LCD L34823. The ALJ finds that, in this case, due to the unique facts and medical research specific to this individual case, LCD L34823 should not be followed.

In this case, the Optune device (tumor treatment field therapy (E0766)) meets the requirements for Medicare coverage because the device/services have been shown to be reasonable and necessary for the treatment of glioblastoma. The FDA has approved Optune as being safe and effective for treating glioblastoma. Further, the documentation demonstrates that the use of Optune in this case, used consistent with the FDA indication, can be expected to provide a favorable outcome and higher quality of life for the Beneficiary. The ALJ finds that the tumor treatment field therapy (E0766), in treatment of the Beneficiary's glioblastoma, stage 4 is a covered benefit under the terms of the Plan.

Conclusions of law

Under the circumstances described in this case, tumor treatment field therapy (E0766) is a covered benefit under the terms of the Plan. The Plan is required to pre-approve and allow coverage for the tumor treatment field therapy (E0766), in treatment of the Beneficiary's glioblastoma, stage 4.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim(s) in accordance with this decision.

Dated: OCT 22 2018

SO ORDERED.


Gary D. Smith

U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City, Missouri

Appeal of:	REDACTED	OMHA Appeal No.: 1-8136384720
Enrollee:	REDACTED	Medicare: Part C
Medicare No.:	REDACTED	Before: Jenifer J. Soulikias Administrative Law Judge

DECISION

After carefully considering the evidence, the undersigned Administrative Law Judge (ALJ) enters a **FULLY FAVORABLE** decision for Beneficiary in this case. An electrical stimulation device for tumor treatment field therapy (TTFT) (HCPCS/ CPT code: E0766) is reasonable and necessary to treat Beneficiary's glioblastoma multiforme, and the Plan shall cover the electrical stimulation device for TTFT (HCPCS/CPT E0766) at issue.

Legend

The following terms apply throughout this decision, unless otherwise noted:

The Plan –Oxford Health Plans (CT), Inc./ AARP Medicare Complete Plan 1 HMO
(UnitedHealthcare)

Beneficiary –REDACTED

Date(s) of service – Pre-approval

Item at issue – Electrical stimulation device for TTFT (HCPCS/ CPT code: E0766).

Procedural History

Beneficiary is enrolled in the Plan, a Medicare Advantage (MA) Plan. Beneficiary submitted a claim for pre-approval to the Plan for an electrical stimulation device for TTFT (HCPCS/ CPT code: E0766) for the treatment of glioblastoma multiforme [GBM or "glioblastoma"]. The Plan denied approval for the device at the initial and redetermination levels of review. The Appellant requested reconsideration from a Part C Qualified Independent Contractor (QIC) (also referred to as an Independent Review Entity), which issued an unfavorable decision on October 11, 2018. (Exh. 1 at 3-4.)

The Office of Medicare Hearings and Appeals (OMHA) received Beneficiary's timely request for an ALJ hearing on November 30, 2018. The amount in controversy meets the requirement for an ALJ hearing. Accordingly, Beneficiary's claim satisfies all the jurisdictional requirements for an ALJ hearing before OMHA.

A telephone hearing was held on January 3, 2019. Beneficiary showed good cause for the submission of additional evidence (*i.e.*, Beneficiary originally was unrepresented at the lower levels of appeal and then, on the eve of the hearing, obtained counsel who presented additional documentation supporting the device and Beneficiary's Medical Records), which is admitted and included in the Record as exhibit 7. Beneficiary appointed counsel to represent her. Bridget Noonan, an attorney with the Parrish Law Offices, and Julie Niles, R.N., appeared and testified on behalf of Beneficiary. The Plan was notified of the hearing, responded, but did not appear.¹ All exhibits were admitted into the Record without objection.

Issues

The issues before the ALJ include all of the issues brought out in the initial determination, coverage determination, or organization determination; redetermination; or reconsideration that were not decided entirely in a party's favor, for the claims or other appealed matters specified in the request for hearing.

Findings of Fact

1. Beneficiary is 67 years old and was enrolled in the Plan in 2018. On July 2, 2018, a right parietal craniotomy and resection of a right parietal brain tumor was performed on Beneficiary. Pathology laboratory testing on the specimen removed confirmed a diagnosis of glioblastoma multiforme. (Exh. 7 at 32-35).

2. Beneficiary received radiation therapy from August 13 to August 31, 2018. (Exh. 7 at 35.)

3. A MGMT promoter methylation test on the tumor was negative. Therefore, temozolomide (TMZ) chemotherapy was contraindicated, and Beneficiary did not undergo chemotherapy. (Exh. 7 at 33, 40; Hearing CD.) Specifically, the Beneficiary's treating physician wrote: "No TMZ because of unmethylated MGMT promoter, her overall performance status, and potential side effects[.]" (Exh. 7 at 40.) TTFT is the only treatment currently available to Beneficiary for treatment of her glioblastoma. (Hearing CD.)

4. A magnetic resonance imaging (MRI) scan completed on August 2, 2018, showed a mass that was suspicious for "residual/recurrent tumor." (Exh. 4 at 9-10.) An MRI on September 20, 2018, was also noted to have been "suspicious for recurrent tumor[.]" (Exh. 7 at 36.)

5. Beneficiary's physician ordered an Optune electrical stimulation device for TTFT (HCPCS/ CPT code: E0766) on September 7, 2018. (Exh. 4 at 4.) The Optune System (formerly known as NovoTTF-100A System) is an electrical stimulation device that delivers alternating electric fields, or Tumor Treating Fields (TTF), to the brain. (Exh. 7 at 7.) The Plan has denied approval for payment for the device and TTFT. (Exh. 1 at 16.)

¹ The ALJ telephone the Plan's representative at the time of the hearing in an attempt to determine whether she still wished to participate and left her a voicemail to advise that she could call in if she wished to join. To date, the ALJ's staff has not been contacted by the Plan's representative that she wished to join the hearing but was unable to do so.

6. There was testimony at the hearing that Beneficiary has “recurrent” glioblastoma. By a preponderance of the evidence of the Record in this case, the ALJ finds that Beneficiary has newly diagnosed glioblastoma. The TTFT was ordered for the treatment of newly diagnosed glioblastoma. An MRI showed a mass that was suspicious for recurrent glioblastoma. Importantly, the ALJ does not have any supporting Medical Records that Beneficiary was diagnosed with recurrent glioblastoma.

7. Glioblastoma is an aggressive, malignant, primary brain tumor. Survival at initial presentation is approximately 10 months, even with aggressive chemotherapy. Because it is extremely rare for glioblastoma to metastasize, it is efficient to treat the disease with regional therapy as part of the treatment strategy. (Exh. 7 at 7 (citing Rulsch et al. “Long-term survival of patients suffering from glioblastoma multiforme treated with tumor-treating fields.” World Journal of Surgical Oncology at 1) (2012).)

8. A large body of peer-reviewed literature shows that tumor treating fields, also known as alternating electric fields, disrupt the cell division process in cancerous tumors which may lead to programmed cell death or apoptosis. Tumor treating fields have shown statistically significant improvement in patient survival and outcomes in glioblastoma brain tumors compared with traditional standard of care alone. (Declaration of Justin Kelly, R.N., Exh. 7 at 2 (CD).)

9. Novocure’s Optune device was approved by the Federal Drug Administration (FDA) through the Premarket Approval (PMA) pathway for the treatment of adult patients with recurrent glioblastoma in April 2011. For recurrent glioblastoma, Optune is indicated following histological- or radiological-confirmed recurrence in the supra-tentorial region of the brain after receiving chemotherapy. The device is intended to be used as monotherapy and is intended as an alternative to standard medical therapy for glioblastoma after surgical and radiation options have been exhausted. (Exh. 7 at 48-51.)

10. In 2015, the FDA approved the Optune device for the treatment of adults with histological-confirmed newly diagnosed glioblastoma. Optune with temozolomide chemotherapy is indicated for the treatment of adult patients with newly diagnosed, supra-tentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy. (Exh. 7 at 48-51.)

11. Since the Optune device was FDA-approved, more than 800 leading oncology centers throughout the United States have been certified to provide and prescribe Optune. (Declaration of Justin Kelly, R.N., Exh. 7 at 2 (CD).)

12. Optune has been prescribed by more than 1200 providers in at all 50 states, Puerto Rico and the District of Columbia. As of July 18, 2018, the Optune device has been prescribed for over 7200 patients in the United States. (Declaration of Justin Kelly, R.N., Exh. 7 at 2 (CD).)

13. The Optune device and its clinical effectiveness have been described in over 140 peer-reviewed publications. (Declaration of Justin Kelly, R.N., Exh. 7 at 2 (CD).)

14. More than 35 commercial payers, including virtually all the large national payers, deem Optune to be reasonable and medically necessary for beneficiaries diagnosed with a glioblastoma, and provide coverage for the device through published coverage policy.

Furthermore, several Medicaid states have adopted positive coverage policies for Optune. (Declaration of Justin Kelly, R.N., Exh. 7 at 2 (CD); *see also* Optune Medical Policies, Exh. 7 at 2 (CD).)

15. United Healthcare, which administers the Plan, is one of the national payers that deem electrical stimulation devices for TTFT to be reasonable and medically necessary for beneficiaries diagnosed with a glioblastoma. The United Healthcare electric tumor treatment field therapy coverage policy dated November 1, 2018, states:

The use of U.S. Food and Drug Administration (FDA) approved devices to generate electric tumor treatment fields (TTF) to treat newly diagnosed histologically-confirmed Supratentorial glioblastoma (known also as glioblastoma multiforme [GBM] or World Health Organization [WHO] grade IV astrocytoma) is proven and medically necessary when used according to FDA labeled indications, contraindications, warnings and precautions, and [additional guidelines].

.....
The use of FDA approved devices to generate electric TTF is proven and medically necessary following radiologically-confirmed recurrence of GBM in the supratentorial region of the brain after initial chemotherapy, and [additional guidelines].

United Healthcare ELECTRIC TUMOR TREATMENT FIELD THERAPY Medical Policy (November 1, 2018), Exh. 7 at 2 (CD).)

16. The National Comprehensive Cancer Network (NCCN) has issued guidelines related to the treatment of glioblastoma. The NCCN indicates that patients under the age of 70 with an initial diagnosis of glioblastoma should receive electric field therapy as part of their initial treatment protocol. (NCCN, *Central Nervous System Cancers: Anaplastic Gliomas/ Glioblastoma*, (Ver. 1.2018), Exh. 7 at 2 (CD).)

17. On August 7, 2018, the Medicare Administrative Contractor (“Contractor”) with jurisdiction over the relevant geographic area issued a letter concerning Novocure’s request for formal reconsideration of the TTFT Local Coverage Determination (LCD), LCD L34823. The Contractor wrote that “[c]urrently, the TTFT LCD includes language indicating that the coverage of TTFT for recurrent glioblastoma multiforme is not reasonable and necessary. **Coverage of newly diagnosed glioblastoma is not addressed.**” (Emphasis added.) The Contractor considered Novocure’s request to revise the LCD to provide for coverage of TTFT for the treatment of adult patients with newly diagnosed supra-tentorial glioblastoma to be valid request due to the submission of new evidence supporting the request. These studies included:

- Stupp R, Taillibert S, Kanner AA, et al. *Maintenance Therapy with Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone For Glioblastoma: A Randomized Clinical Trial*. JAMA. 2015; 314(23):2535-2543.
- Stupp R, Taillibert S, Kanner A, et al. *Effect of Tumor-Treating Fields Plus Maintenance Temozolomide vs Maintenance Temozolomide Alone on Survival in Patients*

With Glioblastoma A Randomized Clinical Trial. JAMA. 2017; 318(23):2306-2316. doi:10.1001/jama.2017.18718.

- Taphoorn MJB, Dirven L, Kanner AA, Lavy-Shahaf G, Weinberg U, Taillibert S, Toms SA, Honnorat J, Chen TC, Sroubek J, David C, Idhah A, Easaw JC, Kim CY, Bruna J, Hottinger AF, Kew Y, Roth P, Desai R, Villano JL, Kirson ED, Ram Z, Stupp R. *Influence of Treatment With Tumor-Treating Fields on Health-Related Quality of Life of Patients With Newly Diagnosed Glioblastoma: A Secondary Analysis of a Randomized Clinical Trial*. JAMA Oncol. 2018 Apr 1; 4(4):495-504. doi: 10.1001/jamaoncol.2017.5082.

(Exh. 7 at 12-14.)

18. The Journal of the American Medical Association (JAMA) published a study of maintenance therapy for newly-diagnosed glioblastoma with tumor-treating fields plus temozolomide versus temozolomide alone on December 15, 2015. The controlled, randomized trial with 695 patients concluded that progression-free survival and overall survival were greater among the patients receiving both tumor treating fields and temozolomide than for patients receiving only temozolomide. Based on the interim analysis of the trial, the study was concluded early. The interim analysis showed that adding tumor treatment fields to temozolomide chemotherapy “significantly prolonged progression-free and overall survival.” (R. Stupp, et al., *Maintenance Therapy with Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma: A Randomized Clinical Trial*, 314 Journal of the American Medical Association 2535 (2015), Exh. 7 at 2 (CD).)

19. On December 19, 2017, JAMA published a study of whether TTFields improves progression-free and overall survival of patients with glioblastoma. The study concluded:

In the final analysis of this randomized clinical trial of patients with glioblastoma who had received standard radiochemotherapy, the addition of TTFields to maintenance temozolomide chemotherapy vs maintenance temozolomide alone, resulted in statistically significant improvement in progression-free survival and overall survival. These results are consistent with the previous interim analysis.

(Stupp R, Taillibert S, Kanner A, et al. *Effect of Tumor-Treating Fields Plus Maintenance Temozolomide vs Maintenance Temozolomide Alone on Survival in Patients With Glioblastoma A Randomized Clinical Trial*. JAMA. 2017; 318(23):2306-2316. doi:10.1001/jama.2017.18718, Exh. 7 at 2 (CD).)

20. On February 1, 2018, JAMA published a study examining the association of TTFields therapy with progression-free survival and HRQoL among patients with glioblastoma. The study concluded:

The addition of TTFields to standard treatment with temozolomide for patients with glioblastoma results in improved survival without a negative influence on HRQoL except for more itchy skin, an expected consequence from the transducer arrays.

(Taphoorn MJB, Dirven L, Kanner AA, Lavy-Shahaf G, Weinberg U, Taillibert S, Toms SA, Honnorat J, Chen TC, Sroubek J, David C, Idhah A, Easaw JC, Kim CY, Bruna J, Hottinger AF, Kew Y, Roth P, Desai R, Villano JL, Kirson ED, Ram Z, Stupp R. *Influence of Treatment With Tumor-Treating Fields on Health-Related Quality of Life of Patients With Newly Diagnosed Glioblastoma: A Secondary Analysis of a Randomized Clinical Trial*. JAMA Oncol. 2018 Apr 1; 4(4):495-504. doi: 10.1001/jamaoncol.2017.5082, Exh. 7 at 2 (CD).)

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with a reconsideration decision is entitled to a hearing before an ALJ from the Department of Health and Human Services provided there is a sufficient amount in controversy and a request for hearing is filed within sixty days after appellant receives the QIC's reconsideration decision. Act § 1869(b)(1)(A), (D) & (E); 42 C.F.R. §§ 405.1002, 422.600.

B. Scope of Review

The ALJ appeals process is governed by 42 C.F.R. §§ 405.1000–1063 except as stated in 42 C.F.R. § 422.562(d). The ALJ considers all issues not decided entirely in appellant's favor in the earlier reviews. 42 C.F.R. § 405.1032(a).

All laws and regulations pertaining to the Medicare and Medicaid programs, including Titles XI, XVIII, and XIX of the Act and applicable implementing regulations, are binding on ALJs. 42 C.F.R. § 405.1063. National Coverage Determinations are also binding upon ALJs. Act § 1869(f)(1); 42 C.F.R. § 405.1060.

And in lieu of binding regulations with the full force and effect of law, the Center for Medicare and Medicaid Services (CMS) and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local coverage determinations (LCDs). ALJs are not bound by but must give substantial deference to LCDs or CMS program guidance when applicable. Act § 1869(f)(2); 42 C.F.R. § 405.1062(b). This includes appeals related to coverage under MA plans under Medicare Part C.²

² Recent Medicare Appeals Council decisions state that it is not appropriate to apply the substantial deference provisions of 42 C.F.R. § 405.1062, which permit an ALJ to depart from an LCD, in claims related to MA plans. To date, no Medicare Appeals Council decision has been designated as precedential, and thus, none is binding. *See* 42 C.F.R. §§ 401.109, 405.1063(c).

The regulations in part 405 of chapter IV of title 42 of the Code of Federal Regulations, concerning the administrative review and hearing processes, apply to ALJ hearings related to MA plans unless subpart M of part 422 provides otherwise. 42 C.F.R. § 422.562(d). Section 422.562(d)(2) contains an exhaustive list of the regulatory provisions of part 405 of chapter IV that do not apply to the administrative review and hearing processes related to MA plan claims:

C. *Standard of Review*

The ALJ is an independent finder-of-fact, conducts a *de novo* review, and issues a decision based on the hearing record. 42 C.F.R. § 405.1000(d). Appellants must furnish sufficient documentary evidence to support the claim. See 42 C.F.R. § 424.5(a)(6). And appellants bear the burden of proof by a preponderance of the evidence. 5 U.S.C. § 556(d) (setting forth the burden of proof to support a proffered position with “reliable, probative, and substantial evidence”).

II. Principles of Law

A. *Medicare Coverage*

Under Medicare Part C, an MA Plan must pay for those items and services (other than hospice benefits) that are available under Medicare Parts A and B or only Part B according to the corresponding enrollment in coverage. Act § 1852; 42 C.F.R. §§ 422.100(a), (c)(1). An enrollee may also purchase supplemental benefits. 42 C.F.R. § 422.100 (c). An MA Plan must provide plan enrollees with coverage of their entitled benefits by “furnishing those benefits directly or through arrangements, or by paying for the benefits.” 42 C.F.R. § 422.100(a).

The Act provides that Medicare covers the rental or purchase of items falling within the definition of durable medical equipment if the equipment is used in the patient’s home or in an

“The following regulations in part 405 of this chapter, and any references thereto, **specifically do not apply** under this subpart [MA plans; Grievances, Organization Determinations and Appeals][.]” (Emphasis added.) Section 422.562(d)(2) does not include section 405.1062 of title 42 as one of the regulations that do not apply the administrative review and hearing processes of MA plan claims. 42 C.F.R. § 422.562(d)(2). Because section 405.1062 is not included in the exhaustive list of sections of part 405 that “specifically do not apply” to MA plan appeals, the provision of section 405.0162(b)—ALJs give applicable LCDs substantial deference—applies to MA plan appeals. Accordingly, the ALJ applies this clear, binding authority.

Section 422.101 of title 42 of the Code of Federal Regulations does not compel a different result. Consistent with section 1852 of the Act, subsection (a) of section 422.101 states that each MA organization must provide coverage of “all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts)[.]” 42 C.F.R. § 422.101(a); *see also* 42 C.F.R. § 422.100. Subsection (b) of section 422.101 states that MA organizations must comply with written coverage decisions of local Medicare contractors. 42 C.F.R. § 422.101(b)(3). But to construe subsection (b) of section 422.101 to require ALJs to be bound by LCDs to deny coverage under an MA plan for items or services that would otherwise be covered would be inconsistent with sections 405.1062, 422.101(a), and 422.562 of title 42. And it would result in the application of the regulations that would be contrary to express provisions of section 1852 of the Act that provides that beneficiaries enrolled in an MA plan are entitled to the same benefits provided to all beneficiaries under Medicare Part B. Therefore, this ALJ construes the regulations contained in sections 405.1062, 422.101, and 422.562 of part 42 as requiring ALJs to give deference to, but to not be bound by, LCDs in making coverage determinations under to MA plans.

institution that is used as a home. Act §§ 1861(s)(6) & 1862(a)(1). *See also* Act § 1861(n) (defining “durable medical equipment”). But to be covered, durable medical equipment must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Act § 1862(a)(1)(A). In addition, Section 1833(e) of the Act requires that all Medicare claims must be supported by sufficient information and documentation.

In addition to the statutes and regulation, the administrative contractor with jurisdiction over the geographic area issued an LCD stating that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. CGS Administrators, LLC, Local Coverage Determination L34823: Tumor Treatment Field Therapy (LCD L34823) (Jan. 2017).

Medicare manuals provide guidance to contractors about developing LCDs. The *Medicare Program Integrity Manual* states that a contractor shall consider a service to be reasonable and necessary if it is:

- Safe and effective;
- Not experimental or investigational; and
- Appropriate, including the duration and frequency that is considered appropriate for the item in terms of whether it is:
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition or to improve the function of a malformed body member;
 - Furnished in a setting appropriate to the patient’s medical needs and condition;
 - Ordered and furnished by qualified personnel;
 - One that meets, but does not exceed, the patient’s medical need; and
 - At least as beneficial as an existing and available medically appropriate alternative.

CMS, *Medicare Program Integrity Manual (MPIM) (Internet-Only Manual Publ’n 100-8)*, ch. 13, § 13.5.1 (Jan. 2013).

Medicare instructs contractors as to the type of evidence to be used in making these technical determinations. Such decisions should be based on either “[p]ublished authoritative evidence” such as “definitive randomized clinical trials” and “general acceptance by the medical community,” with the caveat that “[a]cceptance by individual health care providers” and “limited case studies distributed by sponsors with a financial interest in the outcome[] are not sufficient evidence of general acceptance by the medical community.” *MPIM*, ch. 13, § 13.7.1. In all events, evaluations of reasonableness and necessity “shall be based on the strongest evidence available.” *Id.*

The *MPIM* also states that “LCDs which challenge the standard of practice in a community and specify that an item or service is never reasonable and necessary shall be based on sufficient evidence to convincingly refute evidence presented in support of coverage.” *MPIM*, ch. 13, § 13.7.1. However, “[l]ess stringent evidence is needed when allowing for individual consideration.” *Id.*

The *Medicare Benefit Policy Manual* also provides guidance as to when durable medical equipment may be found to be reasonable and necessary. Durable medical equipment is

necessary when it can be expected to make a meaningful contribution to the treatment of the patient's illness or injury or to the improvement of his or her malformed body member. CMS, *Medicare Benefit Policy Manual (MBPM) (Internet-Only Manual Publ'n 100-2)*, ch. 15, § 110.1(C)(1). As to reasonableness, even though an device may serve a useful medical purpose, the contractor must also consider to what extent it would be reasonable for the Medicare program to pay for the item prescribed, taking into consideration the following questions:

- Would the expense of the item to the program be clearly disproportionate to the therapeutic benefits which could ordinarily be derived from use of the equipment?
- Is the item substantially more costly than a medically appropriate and realistically feasible alternative pattern of care?
- Does the item serve essentially the same purpose as equipment already available to the beneficiary?

MBPM, ch. 15, § 110.1(C)(2).

B. Evidence of Coverage

The Plan's evidence of coverage (EOC) states that it covers everything covered under Medicare Part A and B. (EOC at 4-4, 12-7, Exh. 2 at 59, 248). To be covered, an item or service must be provided according to the coverage guidelines established by Medicare and must be medically necessary. (EOC at 4-3, Exh. 2 at 58.) "Medically necessary" is defined in the Plan as the services, supplies, and equipment needed for the prevention, diagnosis, or treatment of a medical condition under "accepted standards of medical practice." (EOC at 4-3 – 4-4, Exh. 2 at 58-59.) The Plan states:

Generally Accepted Standards of Medical Practice are standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, relying primarily on controlled clinical trials, or, if not available, observational studies from more than one institution that suggests a causal relationship between the service or treatment and health outcomes.

If no credible scientific evidence is available, then standards that are based on Physician specialty society recommendations or professional standards of care may be considered. . . .

(EOC at 4-4, Exh. 2 at 59.) With respect to DME, the Plan states it covers all "medically necessary DME covered by . . . Medicare." (EOC at 4-13, Exh. 2 at 68.) The Plan does not specifically address electrical stimulation devices for TTFT (HCPCS/ CPT code: E0766).

Analysis

I. Jurisdiction

Beneficiary's request for an ALJ hearing was timely and satisfied jurisdictional requirements. On the issues not decided entirely in Appellant's favor in earlier reviews, 42 C.F.R. § 405.1032(a), the ALJ conducted a *de novo* review of the Record.

II. Medicare Coverage

Beneficiary is challenging the denial of coverage for an electrical stimulation device for TTFT (HCPCS/ CPT code: E0766) for the treatment of glioblastoma. After a *de novo* review of the Record, this ALJ finds that there is no LCD applicable to the use of TTFT treatment for newly diagnosed glioblastoma. The evidence in this case established that the use of an electrical stimulation device for TTFT for the treatment of Beneficiary's newly diagnosed glioblastoma was reasonable and necessary. Thus, the device is covered.

MA plans must pay for medical services and items, including durable medical equipment, to the extent that the services or items would be covered under Medicare. 42 C.F.R. § 422.101. To be covered, the item or service must be provided according to the coverage guidelines established by Medicare and must be medically necessary. (EOC at 4-3, Exh. 2 at 58.) "Medically necessary" is defined in the Plan as the services, supplies, and equipment needed for the prevention, diagnosis, or treatment of a medical condition under "accepted standards of medical practice." (EOC at 4-3 – 4-4, Exh. 2 at 58-59.) The Plan and Part C QIC denied coverage in this case on the basis of LCD L34823, which states: "Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary." However, after considering all of the evidence, this ALJ finds that an electronic stimulation device for TTFT is reasonable necessary in this case.

In this case, the electronic stimulation device for TTFT was actually ordered for the treatment of a newly diagnosed glioblastoma. The administrative contractor that issued LCD L34823 recognizes that it does not address coverage for the treatment newly diagnosed glioblastoma, and the administrative contractor is currently considering allowing coverage of electrical stimulation devices for TTFT for treatment of newly diagnosed glioblastoma. Further, there is new evidence supporting coverage for TTFT treatment for newly diagnosed glioblastoma, including studies published in 2015, 2017 and 2018.

And, to the extent that LCD L34823 is applicable, this ALJ gives deference to it but also looks to additional evidence to determine whether the device and service at issue are reasonable and necessary. ALJs must give LCDs substantial deference, but are not bound by them. Act § 1869(f)(2); 42 C.F.R. § 405.1062(b). LCD L34823, states that the administrative contractor considers such TTFT to be categorically non-covered as not medically necessary or reasonable. But after a thorough review of the Record, this ALJ finds that the device at issue for treatment of Beneficiary's glioblastoma is medically reasonable and necessary within the meaning of section 1862(a)(1)(A) of the Social Security Act.

LCD L34823 is an LCD "which challenge[s] the standard of practice in a community and specif[ies] that an item or service is never reasonable and necessary[.]" See *MPIM*, ch. 13, § 13.7.1. LCD L34823, however, is not appropriately "based on sufficient evidence to convincingly refute evidence presented in support of coverage." See *id.* Instead, the LCD only declares that TTFT is not covered. No supporting evidence is submitted. Accordingly, pursuant to Medicare's policy, the ALJ has afforded the LCD substantial deference but looks to the individual consideration of the case.

The *MPIM* instructs that a service is reasonable and necessary when it is: (1) safe and effective; and (2) not experimental or investigational; and (3) appropriate, taking into account

whether the service (a) is furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member, (b) is furnished in a setting appropriate to the patient's medical needs and condition, (c) is ordered and furnished by qualified personnel, (d) meets, but does not exceed, the patient's medical need, and (e) is at least as beneficial as an existing and available medically appropriate alternative. *MPIM, supra* ch. 13, § 13.5.1.

The Optune electrical stimulation device for TTFT at issue received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011. On October 5, 2015, the FDA gave premarket approval for use of Optune in patients with newly diagnosed glioblastoma. While FDA premarket approval does not establish that the device is medically reasonable and necessary pursuant to Medicare requirements, it does ensure that the FDA has closely examined the device and its application. In this case, the FDA determined that sufficient scientific evidence existed to provide the FDA with assurance that the device was safe and effective for its intended use both in patients with recurrent and newly diagnosed glioblastoma. From this perspective, the use of the device meets Medicare guidance requiring that a device be proven safe, effective and not experimental based on authoritative evidence.

In addition to FDA approval, peer-reviewed literature shows that tumor treating fields disrupt the cell division process in cancerous tumors which may lead to programmed cell death or apoptosis. Tumor treating fields have shown statistically significant improvement in patient survival and outcomes in glioblastoma brain tumors compared with traditional standard of care alone. And the Optune device and its clinical effectiveness have been described in over 140 peer reviewed publications. These trials showed that the Optune device is safe, non-investigational and effective.

The use of TTFT for treatment of glioblastoma is also generally accepted by the medical community. Since the Optune device was FDA-approved, more than 800 leading oncology centers throughout the United States have been certified to provide and prescribe Optune. Optune has been prescribed by more than 1200 providers in all 50 states, Puerto Rico and the District of Columbia. As of July 18, 2018, the Optune device has been prescribed for over 7200 patients in the United States. More than 35 commercial payers, including United Healthcare and virtually all the large national payers, deem Optune to be reasonable and medically necessary for beneficiaries diagnosed with a glioblastoma, and provide coverage for the device through published coverage policies. Several Medicaid states have also adopted positive coverage policies for Optune.

And with respect to the medical necessity in this case, a review of the medical records and hearing demonstrated that the device and TTFT are reasonable and necessary for the treatment of Beneficiary's glioblastoma. Beneficiary is 67 years old. She was newly diagnosed with glioblastoma in the supra-tentorial region of the brain in July 2018. A right parietal craniotomy and resection of a right parietal brain tumor was performed. An MGMT promoter methylation test on the tumor was negative, which indicated that chemotherapy was contraindicated. This is expressly stated in Beneficiary's Medical Records. The Beneficiary did complete radiation therapy from August 13 to August 31, 2018. Following completion of radiation therapy, Beneficiary's physician ordered the electrical stimulation device for TTFT. Because chemotherapy was contraindicated, TTFT is the only safe and effective therapy available to Beneficiary. And TTFT is at least as beneficial as an existing and available

medically appropriate alternative. Thus, an electrical stimulation device to provide TTFT is reasonable and necessary to treat Beneficiary's glioblastoma, and is covered by the Plan.

Conclusions of Law

1. Beneficiary established by a preponderance of the evidence that the electrical stimulation device for TTFT (code E0766) at issue is medically reasonable and necessary and meets the requirements for Medicare coverage.
2. The Plan is required to cover the electrical stimulation device for TTFT (code E0766) at issue.
3. All the reasons set forth herein support a **FAVORABLE** decision.

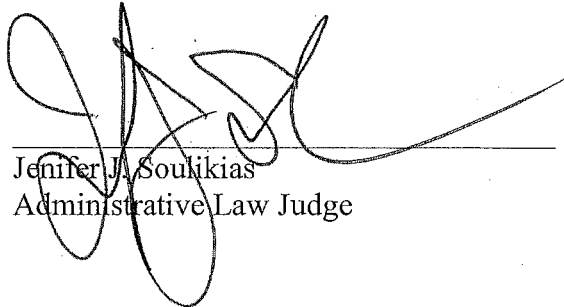
ORDER

The Medicare contractor is **DIRECTED** to process the claims in accordance with this Decision.

SO ORDERED.

Dated:

JAN 18 2019


Jennifer J. Soulikias
Administrative Law Judge



**Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, Missouri**

Appeal of:

ALJ Appeal No.: **1-4878968650**

Enrollee:

Medicare Part: **C**

HICN: *

Before: **Thomas C. Strafuss**
U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, a **FAVORABLE** decision is entered for Appellant/Enrollee ("Enrollee"), .

PROCEDURAL HISTORY

Enrollee disputes the decision of Humana, a Medicare Advantage ("MA") plan, to deny approval of payment for tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment provided through Optune, an out of network supply store. On August 6, 2016, Humana reexamined Enrollee's request for reimbursement for tumor treatment field therapy and affirmed the initial denial. (Exh. 2, p. 96) On August 10, 2016, MAXIMUS Federal Services, a Qualified Independent Contractor ("QIC"), evaluated the claim and issued a decision upholding Humana's decision on the same grounds. (Exh. 1, p. 3)

The Office of Medicare Hearings and Appeals ("OMHA") received Enrollee's timely request for a hearing on August 19, 2016. The requested hearing was held via telephone on October 5, 2016. The Appellant sent in a letter on his own behalf. Dan McCoy appeared telephonically on behalf of Novocure. Cynthia McCloud and Bruce Niebylski, M.D., appeared telephonically on behalf of Humana. The entire case file was admitted into the record without objection.

ISSUE

Whether or not the plan coverage provisions have been met and whether or not payment is warranted.

FINDINGS OF FACT

The following facts were established by a preponderance of the evidence:

1. Enrollee, a male, has been diagnosed with glioblastoma multiforme of the brain (ICD-10 code: C71.9). (Exh. 2, pp. 3-16) Enrollee is now requesting approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment provided through Optune, an out of network supply store. (*Id.*)
2. Enrollee was enrolled in a Humana Medicare Employer PPO Plan. (Exh. 1, p. 31)
3. On June 20, 2016, Humana denied Enrollee's request for approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment and affirmed that decision in redetermination. (Exh. 1, p. 12; Exh. 2, p. 96) Humana's reason for denial was that Local Coverage Determination ("LCD") L34823 regarding tumor treatment field therapy states that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. (*Id.*)
4. On August 10, 2016, the QIC examined Enrollee's claim and affirmed Humana's denial of coverage. (Exh. 1, p. 3)

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

An individual or an organization who is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services ("HHS") provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. The Social Security Act (the Act), Title XVIII, section 1869(b)(1)(A); *see* 42 C.F.R. § 405.1014. In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to the Office of Medical Hearings and Appeals ("OMHA"). *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005). The Administrative Law Judges ("ALJ") within OMHA issue the final decisions of the Secretary unless later reviewed by the Medicare Appeals Council. *Id.*

For requests filed in calendar years 2010 through 2012, the minimum amount remaining in controversy required for an ALJ hearing is \$130.00 (following application of any co-insurance or deductible), \$140.00 for calendar years 2013 and 2014, and, beginning January 1, 2015, \$150.00. *See* § 1869(b)(1)(E) of the Act, 74 Fed. Reg. 48976 (Sept. 2, 2009), 77 Fed. Reg. 59619 (Sept. 28, 2012), 42 C.F.R. § 405.1006(b), and 42 C.F.R. § 405.1006(d)(1)(ii).

To be considered timely, the request for hearing must be received by OMHA within sixty days after an appellant receives the QIC's reconsideration decision. An appellant is presumed to have received the QIC's reconsideration five days after the date noted on the first page of the reconsideration unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3).

In this case, Appellant timely requested a hearing before an ALJ. 42 C.F.R. § 405.1014. The remaining amount in controversy meets the jurisdictional requirements for a hearing. 42 C.F.R. § 405.1006.

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in the appellant's favor. 42 C.F.R. § 405.1032. However, if evidence presented before or during the hearing causes the ALJ to question a fully favorable decision, he or she will notify the appellant and will consider it an issue at the hearing. *Id.*

An ALJ may issue a decision on the record on his or her own initiative if the evidence in the hearing record supports a fully favorable finding. 42 C.F.R. §§ 405.1000(g) and 405.1038(a). In addition, if all parties to the hearing waive their right to appear at the hearing, the ALJ may make a decision based on the evidence that is in the record and any new evidence that is admitted by the ALJ. 42 C.F.R. § 405.1000(e).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue. 42 C.F.R. § 405.1000(d) and Section 557 of the Administrative Procedures Act. A *de novo* review requires the ALJ to review and evaluate the evidence without regard to the findings in the prior determinations on the claim and make an independent assessment in reliance upon the evidence and controlling laws. All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Act and applicable implementing regulations, are binding on the ALJ. 42 C.F.R. § 405.1063.

An appellant has the burden of proving each element of a Medicare claim by a preponderance of the evidence (satisfied through the submission of sufficient evidence in accordance with Medicare rules). *See* Sections 1814(a)(1), 1815(b), and 1833(e) of the Act; *see also* 42 C.F.R. §§ 424.5(a)(6), 405.1018, 405.1028, and 405.1030.

II. Principles of Law

The Medicare program, Title XVIII of the Social Security Act, is administered through the Centers for Medicare and Medicaid Services, a component of the United States Department of Health and Human Services ("HHS"). Title XVIII, §1832 of the Act describes the scope of benefits provided for by Medicare and provides that those benefits shall include "medical and other health services." In addition, section 1862(a)(1)(A) of the Social Security Act provides for coverage and payment for those services and supplies only when those services or supplies are considered to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

The obligations of a Medicare Advantage (“MA”) Organization to its enrollees are set forth in §1852 of the Act. 42 C.F.R. §422 establishes standards, requirements, limitations, and procedures for Medicare services furnished or paid for via MA plans. Pursuant to 42 C.F.R. §422.100, MA Organizations must provide their members with the same benefits provided under Parts A and B of Medicare. According to 42 C.F.R. § 422.111, MA Organizations are required to make certain disclosures to its enrollees regarding its services and benefits. These disclosures include the plan’s service area, benefits, and exclusions from coverage. *Id.*

Local Coverage Determination (“LCD”) L34823 regarding tumor treatment field therapy states:

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

ANALYSIS

Enrollee, _____, has been diagnosed with glioblastoma multiforme of the brain (ICD-10 code: C71.9). (Exh. 2, pp. 3-16) Enrollee is now requesting approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment provided through Optune, an out of network supply store. (*Id.*) Enrollee was enrolled in a Humana Medicare Employer PPO Plan. (Exh. 1, p. 31)

On June 20, 2016, Humana denied Enrollee’s request for approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment and affirmed that decision in redetermination. (Exh. 1, p. 12; Exh. 2, p. 96) Humana’s reason for denial was that Local Coverage Determination (“LCD”) L34823 regarding tumor treatment field therapy states that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. (*Id.*) On August 10, 2016, the QIC examined Enrollee’s claim and affirmed Humana’s denial of coverage. (Exh. 1, p. 3)

The obligations of a Medicare Advantage (“MA”) Organization to its enrollees are set forth in §1852 of the Act. 42 C.F.R. §422 establishes standards, requirements, limitations, and procedures for Medicare services furnished or paid for via MA plans. Pursuant to 42 C.F.R. §422.100, MA Organizations must provide their members with the same benefits provided under Parts A and B of Medicare.

The Medicare Contractor CGS Administrators, LLC, created a Local Coverage Determination addressing the issue in this case. That LCD simply states that tumor treating fields therapy will be denied as not reasonable and necessary. There is no additional detail or guidance contained within the LCD. The only substance is a reference section entitled “Sources of Information and Basis for Decision.” That section lists seventeen separate citations which presumably support the summary conclusion that tumor treating fields therapy is not reasonable and necessary. The list is noteworthy in that the most recent citation is from 2013.

Pursuant to section 1869(f)(2) of the Act, Administrative Law Judges are to give substantial deference to Local Coverage Determinations. If an ALJ does not follow an applicable LCD, an explanation must be given. The ALJ chooses to deviate from the LCD for the following reasons.

Tumor treating fields therapy using an electric stimulation device is FDA approved. FDA approval necessarily means the treatment has been deemed safe and effective. The most recent phase three clinical trial,¹ published in December 2015 shows that this treatment is effective because it significantly prolongs the disease progression of glioblastoma and increases the overall odds of survival. The 2015 study is given greater weight than the LCD both because it is recent proof of efficacy and because the LCD lacks any substantive guidance. Finally, the Enrollee suffers from glioblastoma. Dr. Mohamed Hamza wrote a letter in support of tumor treating field therapy for the Enrollee, and believed that the tumor treatment therapy, in combination with temozolomide, is the most appropriate option for his care. Therefore the ALJ concludes that tumor treating field therapy was medically reasonable and necessary in this case, and Medicare covers this service.

Subsequently because Medicare Parts A and B will cover the tumor treatment field therapy at issue then Humana is required to cover the services as well.

The undersigned concludes that Medicare coverage is available for the tumor treatment field therapy requested by the Enrollee. The services requested are covered under Medicare Parts A or B and thus Medicare Part C coverage must be approved.

CONCLUSIONS OF LAW

The undersigned concludes Humana does have to cover tumor treatment field therapy requested by the Enrollee.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim herein in accordance with this decision.

OCT 14 2016

SO ORDERED

Dated: _____


Thomas C. Strafuss

U.S. Administrative Law Judge

¹ Stupp R., Taillibert S., Kanner A., et al. Maintenance Therapy With Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma: A Randomized Clinical Trial. *JAMA*. 2015; 314(23): 2535-2543. Doi:10.1001/jama.2015.16669. See <http://jama.jamanetwork.com/article.aspx?articleid=2475463>. (Exh. 2, p. 17)



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, Missouri

Appeal of: }	ALJ Appeal No.: 1-7755211044
Enrollee:	Medicare Part: C
HICN: ****9387A	Before: Thomas C. Strafuss U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, a **FAVORABLE** decision is entered for Appellant/Enrollee,

PROCEDURAL HISTORY

Enrollee disputes the decision of Humana Insurance Company, a Medicare Advantage (“MA”) plan, to deny approval of payment for tumor treatment field therapy. On June 22, 2018, Humana reexamined Enrollee’s request for reimbursement for tumor treatment field therapy and affirmed the initial denial. (Exh. 1, pp. 15-17) On July 27, 2018, MAXIMUS Federal Services, a Qualified Independent Contractor (“QIC”), evaluated the claim and issued a decision upholding Humana’s decision on the same grounds. (Exh. 1, pp. 1-2)

The Office of Medicare Hearings and Appeals (“OMHA”) received Enrollee’s timely request for a hearing on August 3, 2018. The requested hearing was held via telephone on September 19, 2018. Julie Miles and Stephanie Hales appeared telephonically on behalf of Novocure. Marcia Taylor and Bryan Carr, M.D., appeared telephonically on behalf of Humana. The case file was admitted into the record without objection.

ISSUE

Whether or not the plan coverage provisions have been met and whether or not payment is warranted.

FINDINGS OF FACT

The following facts were established by a preponderance of the evidence:

1. Enrollee, a 70 year old male, has been diagnosed with glioblastoma multiforme of the brain (ICD-10 code: C71.3). (Exh. 2, pp. 1-18) Enrollee is now requesting approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment provided through Optune, an out of network supply store. (*Id.*)
2. Enrollee has been enrolled in a Humana Choice H5216-078 (PPO). (Exh. 1, p. 68)
3. On June 22, 2018, Humana denied Enrollee's request for approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment and affirmed that decision in redetermination. (Exh. 1, pp. 15-17) Humana's reason for denial was that Local Coverage Determination ("LCD") L34823 regarding tumor treatment field therapy states that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. (*Id.*)
4. On July 27, 2018, the QIC examined Enrollee's claim and affirmed Humana's denial of coverage. (Exh. 1, pp. 1-2)

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services, provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. *See* Social Security Act (the Act), Title XVIII, § 1869(b)(1)(A); *see also* 42 C.F.R. § 405.1014. The Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, unless later reviewed by the Medicare Appeals Council. *Id.*

To be considered timely, the request for hearing must be received by OMHA within sixty days after an appellant receives the QIC's reconsideration decision. An appellant is presumed to have received the QIC's reconsideration five days after the date noted on the first page of the reconsideration unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3).

B. Scope of Review

The ALJ considers all issues not decided entirely in the appellant's favor at any prior level of review. 42 C.F.R. § 405.1032. The ALJ may give notice to the parties if any other issue will be addressed at the hearing. *Id.* The ALJ may also issue a decision on the record on his or her own

initiative if the evidence in the hearing record supports a fully favorable finding. 42 C.F.R. § 405.1000(g) and § 405.1038(a).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue. 42 C.F.R. § 405.1000(d) and Section 557 of the Administrative Procedures Act. A *de novo* review requires the ALJ to review and evaluate the evidence without regard to the findings in the prior determinations on the claim and make an independent assessment in reliance upon the evidence and controlling laws. All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Act and applicable implementing regulations, are binding on the ALJ. 42 C.F.R. § 405.1063.

An appellant has the burden of proving each element of a Medicare claim by a preponderance of the evidence (satisfied through the submission of sufficient evidence in accordance with Medicare rules). See § 1814(a)(1), § 1815(b), and § 1833(e) of the Act; see also 42 C.F.R. § 424.5(a)(6), § 405.1018, § 405.1028, and § 405.1030.

II. Principles of Law

The Medicare program, Title XVIII of the Social Security Act, is administered through the Centers for Medicare and Medicaid Services, a component of the United States Department of Health and Human Services (“HHS”). Title XVIII, § 1832 of the Act describes the scope of benefits provided for by Medicare and provides that those benefits shall include “medical and other health services.” In addition, § 1862(a)(1)(A) of the Social Security Act provides for coverage and payment for those services and supplies only when those services or supplies are considered to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

The obligations of a Medicare Advantage (“MA”) Organization to its enrollees are set forth in §1852 of the Act. 42 C.F.R. §422 establishes standards, requirements, limitations, and procedures for Medicare services furnished or paid for via MA plans. Pursuant to 42 C.F.R. §422.100, MA Organizations must provide their members with the same benefits provided under Parts A and B of Medicare. According to 42 C.F.R. § 422.111, MA Organizations are required to make certain disclosures to its enrollees regarding its services and benefits. These disclosures include the plan’s service area, benefits, and exclusions from coverage. *Id.*

Local Coverage Determination (“LCD”) L34823 regarding tumor treatment field therapy states:

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ANALYSIS

Enrollee, a 70 year old male, has been diagnosed with glioblastoma multiforme of the brain (ICD-10 code: C71.3). (Exh. 2, pp. 1-18) Enrollee is now requesting approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment provided through Optune, an out of network supply store. (*Id.*) Enrollee has been enrolled in a Humana Choice H5216-078 (PPO). (Exh. 1, p. 68)

On June 22, 2018, in redetermination, Humana denied Enrollee's request for approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment. (Exh. 1, pp. 15-17) Humana's reason for denial was that Local Coverage Determination ("LCD") L34823 regarding tumor treatment field therapy states that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. (*Id.*) On July 27, 2018, the QIC examined Enrollee's claim and affirmed Humana's denial of coverage. (Exh. 1, pp. 1-2)

The obligations of a Medicare Advantage ("MA") Organization to its enrollees are set forth in §1852 of the Act. 42 C.F.R. §422 establishes standards, requirements, limitations, and procedures for Medicare services furnished or paid for via MA plans. Pursuant to 42 C.F.R. §422.100, MA Organizations must provide their members with the same benefits provided under Parts A and B of Medicare.

The Medicare Contractor CGS Administrators, LLC, created a Local Coverage Determination addressing the issue in this case. That LCD simply states that tumor treating field therapy will be denied as not reasonable and necessary. There is no additional detail or guidance contained within the LCD as to why tumor treatment field therapy should not be compensated by Medicare. The only substance is a reference section entitled "Sources of Information and Basis for Decision." That section lists seventeen separate citations which presumably support the summary conclusion that tumor treating fields therapy is not reasonable and necessary. The list is noteworthy in that the most recent citation is from 2013.

Pursuant to section 1869(f)(2) of the Act, Administrative Law Judges are generally required to give substantial deference to Local Coverage Determinations. If an ALJ does not follow an applicable LCD, an explanation must be given. The ALJ chooses to deviate from the LCD for the following reasons. The FDA issued a premarket approval of Optune (a tumor treatment field therapy device) consistent with the prescribed use by the treating physician on November 2, 2015. (Exh. 4, pp. 10-11)¹ FDA approval generally means the treatment has been deemed safe and effective. The most recent phase three clinical trial submitted by Novocure,² published in December 2015, shows that this treatment is effective because it significantly prolongs the disease progression of glioblastoma, and increases the overall odds of survival. The 2015 study is given greater weight than the LCD both because it is recent proof of efficacy and because the LCD lacks any substantive guidance. Further, the 2018 National Comprehensive Cancer Network ("NCCN") Guidelines allow for alternating use of electric field therapy with temozolomide when treating glioblastoma. (Exh. 2, pp. 20-21.) Finally, the Enrollee suffers from glioblastoma, which is the very condition/cancer this device is designed to treat. Therefore the

¹ The FDA had issued an earlier approval for Optune (NOVOTFF -100A System) on May 6, 2011. The approval was limited to the recurrence of glioblastoma multiform after receiving chemotherapy. The current FDA approval includes newly diagnosed GBM following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy. (*Id.*)

² Stupp R., Taillibert S., Kanner A., et al. Maintenance Therapy With Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma: A Randomized Clinical Trial. *JAMA*. 2015; 314(23): 2535-2543. Doi:10.1001/jama.2015.16669. See <http://jama.jamanetwork.com/article.aspx?articleid=2475463>

ALJ concludes that tumor treating field therapy was medically reasonable and necessary in this case, and Medicare covers this service.

The same result would be reached under traditional Medicare.

The undersigned concludes that Medicare coverage is available for the tumor treatment field therapy requested by the Enrollee. The services requested are covered under Medicare Parts A or B and thus Medicare Part C coverage must be approved.

CONCLUSIONS OF LAW

The undersigned concludes Humana does have to cover the tumor treatment field therapy requested by the Enrollee.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim herein in accordance with this decision.

SO ORDERED,

Dated: SEP 27 2018



Thomas C. Strafuss

U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, Missouri

Appeal of:	ALJ Appeal No.: 1-7904907371
Enrollee:	Medicare Part: C
HICN: ****2548A	Before: Thomas C. Strafass U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, a **FAVORABLE** decision is entered for Appellant/Enrollee,

PROCEDURAL HISTORY

Enrollee disputes the decision of Amerigroup Tennessee, Inc. (Amerigroup), a Medicare Advantage ("MA") plan, to deny preapproval of payment for tumor treatment field therapy. On July 20, 2018, Amerigroup reexamined Enrollee's request for reimbursement for tumor treatment field therapy and affirmed the initial denial. (Exh. 1, pp. 33-34) On July 23, 2018, MAXIMUS Federal Services, a Qualified Independent Contractor ("QIC"), evaluated the claim and issued a decision upholding Amerigroup's decision. (Exh. 1, pp. 5-6)

The Office of Medicare Hearings and Appeals ("OMHA") received Enrollee's timely request for a hearing on September 21, 2018. The requested hearing was held via telephone on November 13, 2018. Julie Miles and Dan McCoy appeared telephonically on behalf of Appellant and Novocure. Lynette Cooper and Terri Puzycki appeared telephonically on behalf of Amerigroup. The case file was admitted into the record without objection, including additional recent articles and documents submitted with good cause. No additional medical evidence was submitted.

ISSUE

Whether or not the plan coverage provisions have been met and whether or not payment is warranted.

FINDINGS OF FACT

The following facts were established by a preponderance of the evidence:

1. Enrollee, a 63 year old male, has been newly diagnosed with malignant neoplasm of the temporal lobe (ICD-10 code: C71.2). (Exh. 2, pp. 1-26) Enrollee is now requesting approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment provided through Optune, an out of network supply store. (*Id.*)
2. Enrollee has been enrolled in an Amerivantage Plus (HOM). (Exh. 1, p. 68)
3. On July 20, 2018, Amerigroup denied Enrollee's request for preapproval for the payment of tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment and affirmed that decision in redetermination. (Exh. 1, pp. 33-34) Amerigroup's reason for denial was that Local Coverage Determination ("LCD") L34823 regarding tumor treatment field therapy states that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. (*Id.*)
4. On July 23, 2018, the QIC examined Enrollee's claim and affirmed Amerigroup's denial of coverage. (Exh. 1, pp. 5-6)

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services, provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. *See* Social Security Act (the Act), Title XVIII, § 1869(b)(1)(A); *see also* 42 C.F.R. § 405.1014. The Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, unless later reviewed by the Medicare Appeals Council. *Id.*

To be considered timely, the request for hearing must be received by OMHA within sixty days after an appellant receives the QIC's reconsideration decision. An appellant is presumed to have received the QIC's reconsideration five days after the date noted on the first page of the reconsideration unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3).

B. Scope of Review

The ALJ considers all issues not decided entirely in the appellant's favor at any prior level of review. 42 C.F.R. § 405.1032. The ALJ may give notice to the parties if any other issue will be addressed at the hearing. *Id.* The ALJ may also issue a decision on the record on his or her own

initiative if the evidence in the hearing record supports a fully favorable finding. 42 C.F.R. § 405.1000(g) and § 405.1038(a).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue. 42 C.F.R. § 405.1000(d) and Section 557 of the Administrative Procedures Act. A *de novo* review requires the ALJ to review and evaluate the evidence without regard to the findings in the prior determinations on the claim and make an independent assessment in reliance upon the evidence and controlling laws. All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Act and applicable implementing regulations, are binding on the ALJ. 42 C.F.R. § 405.1063.

An appellant has the burden of proving each element of a Medicare claim by a preponderance of the evidence (satisfied through the submission of sufficient evidence in accordance with Medicare rules). *See* § 1814(a)(1), § 1815(b), and § 1833(e) of the Act; *see also* 42 C.F.R. § 424.5(a)(6), § 405.1018, § 405.1028, and § 405.1030.

II. Principles of Law

The Medicare program, Title XVIII of the Social Security Act, is administered through the Centers for Medicare and Medicaid Services, a component of the United States Department of Health and Human Services (“HHS”). Title XVIII, § 1832 of the Act describes the scope of benefits provided for by Medicare and provides that those benefits shall include “medical and other health services.” In addition, § 1862(a)(1)(A) of the Social Security Act provides for coverage and payment for those services and supplies only when those services or supplies are considered to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

The obligations of a Medicare Advantage (“MA”) Organization to its enrollees are set forth in §1852 of the Act. 42 C.F.R. §422 establishes standards, requirements, limitations, and procedures for Medicare services furnished or paid for via MA plans. Pursuant to 42 C.F.R. §422.100, MA Organizations must provide their members with the same benefits provided under Parts A and B of Medicare. According to 42 C.F.R. § 422.111, MA Organizations are required to make certain disclosures to its enrollees regarding its services and benefits. These disclosures include the plan’s service area, benefits, and exclusions from coverage. *Id.*

Local Coverage Determination (“LCD”) L34823 regarding tumor treatment field therapy states:

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

ANALYSIS

Enrollee, a 63 year old male, has been diagnosed with malignant neoplasm of the temporal lobe (ICD-10 code: C71.2). (Exh. 2, pp. 1-26) Enrollee is now requesting approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment provided through Optune, an out of network supplier/provider. (*Id.*) Enrollee has been enrolled in an Amerivantage Plus (HOM). (Exh. 1, p. 68)

On July 20, 2018, Amerigroup denied Enrollee's request for approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment and affirmed that decision in redetermination. (Exh. 1, pp. 33-34) Amerigroup's reason for denial was that Local Coverage Determination ("LCD") L34823 regarding tumor treatment field therapy states that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. (*Id.*)

On July 23, 2018, the QIC examined Enrollee's claim and affirmed Amerigroup's denial of coverage. (Exh. 1, pp. 5-6)

The obligations of a Medicare Advantage ("MA") Organization to its enrollees are set forth in §1852 of the Act. 42 C.F.R. §422 establishes standards, requirements, limitations, and procedures for Medicare services furnished or paid for via MA plans. Pursuant to 42 C.F.R. §422.100, MA Organizations must provide their members with the same benefits provided under Parts A and B of Medicare.

The Medicare Contractor CGS Administrators, LLC, created a Local Coverage Determination addressing the issue in this case. That LCD simply states that tumor treating field therapy will be denied as not reasonable and necessary. There is no additional detail or guidance contained within the LCD as to why tumor treatment field therapy should not be compensated by Medicare. The only substance is a reference section entitled "Sources of Information and Basis for Decision." That section lists seventeen separate citations which presumably support the summary conclusion that tumor treating fields therapy is not reasonable and necessary. The list is noteworthy in that the most recent citation is from 2013.

Pursuant to § 1869(f)(2) of the Act, Administrative Law Judges are generally required to give substantial deference to Local Coverage Determinations. If an ALJ does not follow an applicable LCD, an explanation must be given. The ALJ chooses to deviate from the LCD for the following reasons. The FDA issued a premarket approval of Optune (a tumor treatment field therapy device) consistent with the prescribed use by the treating physician on November 2, 2015. (Exh. 6, pp. 1)¹ FDA approval generally means the treatment has been deemed safe and effective. The most recent phase three clinical trial submitted by Novocure,² published in December 2015, shows that this treatment is effective because it significantly prolongs the disease progression of glioblastoma, and increases the overall odds of survival. (Exh. 2, pp. 67-76) The 2015 study is given greater weight than the LCD both because it is recent proof of efficacy and because the LCD lacks any substantive guidance. This study was also updated with new data and analysis showing continued positive results in articles dated December 19, 2017, and February 1, 2018. (Exh. 5, pp. 5-25) Further, the 2018 National Comprehensive Cancer

¹ The FDA had issued an earlier approval for Optune (NOVOTFF -100A System) on May 6, 2011. The approval was limited to the recurrence of glioblastoma multiform after receiving chemotherapy. The current FDA approval includes newly diagnosed GBM following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy. (*Id.*)

² Stupp R., Taillibert S., Kanner A., et al. Maintenance Therapy With Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma: A Randomized Clinical Trial. *JAMA*. 2015; 314(23): 2535-2543. Doi:10.1001/jama.2015.16669. See <http://jama.jamanetwork.com/article.aspx?articleid=2475463>

Network ("NCCN") Guidelines allow for alternating use of electric field therapy with temozolomide when treating glioblastoma. (Exh. 2, pp. 27-30.) Finally, CGS Administrators, a DME Medicare Administrative Contractor, stated in an August 7, 2018, letter to Novocure that LCD L34823 does not pertain to newly diagnosed glioblastoma multiforme ("GBM") which is inconsistent with their reiteration in the same letter that recurrent GBM is still not covered. (Exh. 5, pp. 27-29) In summation, the Enrollee suffers from newly diagnosed glioblastoma, which is the very condition/cancer this device is designed to treat. Together this documentation supports the conclusion that the Optune device is safe and effective and no longer experimental or investigational. Therefore, while the ALJ does not reject the LCD, the ALJ declines to give it controlling weight, especially after considering the letter from CGS Administrators. The ALJ concludes that tumor treating field therapy was medically reasonable and necessary in this case, and Medicare covers this service.

The same result would be reached under traditional Medicare.

The undersigned concludes that Medicare coverage is available for the tumor treatment field therapy requested by the Enrollee. The services requested are covered under Medicare Parts A or B and thus Medicare Part C coverage must be approved.

CONCLUSIONS OF LAW

The undersigned concludes Amerigroup does have to cover the tumor treatment field therapy requested by the Enrollee.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim herein in accordance with this decision.

SO ORDERED,

Dated: NOV 28 2018


Thomas C. Strafuss

U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Irvine, California

Appeal of:

[REDACTED]

OMHA Appeal No.: 1-8067635107

Enrollee:

[REDACTED]

Medicare: Part C

Medicare No.: *****7012A

Before: James M. Takos
U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, a **FULLY FAVORABLE** decision is entered for Appellant/Enrollee, **R. Stockton** (hereinafter "Appellant").

PROCEDURAL HISTORY

On or about September 24, 2018, Novocure, a non-Medicare contracted DME Supplier, on behalf of the Appellant, requested pre-approval from CIGNA Healthspring Achieve Plus SNP ("CIGNA"), the Medicare Advantage Prescription Drug HMO Plan of which the Appellant is an Enrollee, for an electrical stimulation device (Optune) and Transducer Array, the subject DME comprising Tumor Treatment Field Therapy (TTFT) used for the treatment of Glioblastoma Multiforme (GBM) as a 6-month rental (6 total units). On September 25, 2018, CIGNA issued a denial of the organization determination for Optune and Transducer Arrays, indicating that their medical director determined that the requested items were not approvable as the items were not covered by Medicare. On October 24, 2018, CIGNA received an appeal request from Novocure on behalf of the Appellant. On or about October 25, 2018, CIGNA reiterated its denial, stating that based upon Local Coverage Determination for TTFT (L34823), TTFT (HCPCS Code E0766) will be denied as not medically reasonable and necessary, as it constituted an experimental medical/surgical procedure. (Ex. 1, pg. 15)

On or about October 29, 2018, following a Request for Reconsideration by Novocure, the assigned Independent Review Entity (IRE), Maximus Federal Services ("Maximus") issued a denial of pre-approval of the Optune system, affirming CIGNA's denial with the following as its rationale: "We decided that CIGNA does not have to pre-approve Tumor Treatment Field Therapy ("TTFT") for the Enrollee. You asked CIGNA to pre-approve TTFT. You say that TTFT is medically necessary for the Enrollee. CIGNA denied your request. CIGNA says TTFT is not covered by Medicare. CIGNA must follow Medicare rules. Medicare rules specifically state TTFT is not covered by Medicare. Therefore, we decided that CIGNA does not have to pre-approve TTFT (HSCPC Code E0766) for the Enrollee. (Ex. 1, pg. 1)

The Appellant filed a timely request with the Office of Medicare and Appeals (OMHA) for a hearing before an Administrative Law Judge (ALJ) and the amount in controversy satisfies the jurisdictional requirement for this action. *See* 42 C.F.R. §§405.1006 and 405.104. This matter is properly before the undersigned ALJ. Pursuant to a written notice, a telephonic hearing was held on December 6, 2018, at the Office of Medicare Hearings and Appeals, Irvine Field Office, Irvine, California. The Appellant's Representative, Attorney Deborah Parrish, appeared and provided testimony on behalf of the Appellant. The Appellant was further represented by the following Party participants: [REDACTED], Medical Power of Attorney and wife of the Party Appellant; Julie Miles, Registered Nurse employed by Novocure; and Christopher Dardis, M.D., Neuro Oncologist and Staff Physician for Barrow Neuro Oncology. The MAO Plan, CIGNA Healthspring Achieve Plus SNP, was represented by the following Party Appellants: Amanda Clark, Appeals Associate, CIGNA, Megan Myers, Closing Supervisor, CIGNA, Rudolph C. Cane, M.D., Medical Director for CIGNA, Part C Appeals. No appearance was made by the assigned Part C IRE, Maximus Federal Services. All Exhibits were admitted into the record without objection at the time of the ALJ Hearing.¹ The record was closed and the matter was taken under submission for a decision. (Hearing CD)

ISSUES

The Part C Independent Review Entity (IRE), Maximus Federal Services, concluded that the Medicare Advantage Organization, CIGNA Healthspring Achieve Plus SNP ("CIGNA"), was justified in its denial of pre-approval of coverage of the Optune TTFT system, as requested by the Appellant. The issue to be determined by the Administrative Law Judge (ALJ) is:

Whether the pre-approval of rental of the Optune Plus Transducer system was met the conditions of payment as a valid treatment option for Glioblastoma Multiforme (GBM) within the context of an in-network exception as requested by the Appellant/Enrollee, R. Stockon, and was thus subject to reimbursement pursuant to §§1851-1859 (Medicare Part C) of Title XVIII of the Social Security Act;

- i) Whether the respondent Medicare Advantage Organization, CIGNA, was compliant with Medicare's requirements of access to Part A and B benefits, and disclosure requirements with respect to costs billed by the Appellant for DME supplies to include the subject Optune system pursuant to 42 C.F.R. §§422.2 and 422.111;
- i) If CIGNA was not compliant with Medicare's access to Medicare benefits and disclosure requirements, whether the Appellant is eligible for pre-approval of previously-denied coverage of the subject Optune system.

FINDINGS OF FACT

¹ The undersigned notes that the Appellant's Representative, Attorney Parrish, made a proffer of additional documents which were received at the date of the subject ALJ Hearing of December 6, 2018. The undersigned finds there is a lack of good cause pursuant to 42 C.F.R. §405.1018(c), as the materials were submitted the date of hearing, without explanation as to why they had not been submitted with the Request for Hearing, or were not timely submitted due to unforeseen circumstances. Therefore, the materials proffered will not be entered into evidence.

The following facts are established by a preponderance of the evidence.

1. The Appellant is a 72 year-old male (date of birth of January 31, 1946) enrolled with CIGNA Healthspring Achieve Plus SNP, effective January 1, 2014. (Ex. 1, pg. 17; Ex. 2, pg. 6)
2. On or about May 4, 2018, the Appellant presented to Barrow Neuro Oncology with complaint of word finding difficulty and olfactory auras which he had been experiencing since March 14, 2014. MRI of the brain revealed a left insular tumor, which was resected through surgery on May 8, 2018. The Appellant is status post radiation treatment and Temozolomide, with adjuvant Temozolomide commencing at or near August 19, 2018. (Ex. 2, pgs. 4, 6)
3. The record contains the Optune Prescription Form dated September 17, 2018 as drafted by Dr. Dardis, for the Optune Transducer Array, for a period of six months. The Prescription is supported by Encounter Notes as drafted by Barrow Neuro Oncology dated September 18, 2018. (Ex. 2, pgs. 4, 6)
3. Finally, the record contains CIGNA's Evidence of Coverage for 2018. The EOC states that the Plan must cover all services covered by original Medicare's Coverage rules, as well as the Plan's limitations or exclusions of coverage to include: experimental medical and surgical supplies (those determined by the Plan and original Medicare to not be generally accepted by the medical community. (Ex. 1, pg. 81)

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) §1869(b)(1)(A)

In implementing this statutory directive, the Secretary has delegated his authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *Id.*

A hearing before an ALJ is only available if the remaining amount in controversy is \$140 or more. *See* CMS Rul. 02-1, 67 Fed. Reg. 62478, 62480 (Oct. 7, 2002); 77 Fed. Reg. 58916 (September 28, 2012). The request for hearing is timely if filed within sixty days after receipt of a Carrier Hearing Officer decision. *See* 20 C.F.R. §404.933(b)(1)

B. Scope of Review

Under the Centers for Medicare and Medicaid Services' (CMS) implementation policy for the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. Law 106-554, app. F, 114 Stat. 2763, 2763A-463, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. Law 108-173, 117 Stat. 2066, all initial determinations by CMS contracted Carriers prior to January 1, 2006, are governed by the ALJ hearing procedures set forth at 20 C.F.R. §§ 404.929 through 404.961 and 42 C.F.R. §405.855. *See* 70 Fed. Reg. 11420, 11424-26 (Mar. 8, 2005).

"The issues before the Administrative Law Judge include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in [the Appellant's] favor. However, if evidence presented before or during the hearing causes the Administrative Law Judge to question a fully favorable determination, he or she will notify [the Appellant] and will consider it an issue at the hearing." 20 C.F.R. §404.946(a)

"The Administrative Law Judge may decide a case on the record and not conduct an oral hearing if [the Appellant] and all the parties indicate in writing that [they] do not wish to appear before the Administrative Law Judge at an oral hearing." 20 C.F.R. § 404.948(b)(i)

C. Standard of Review

"The [Office of Medicare Hearings and Appeals]...is staff[ed] with Administrative Law Judges who conduct 'de novo' hearings...." 70 Fed. Reg. 36386 (June 23, 2005); *see also In re Atlantic Anesthesia Associates, P.C.*, MAC (June 2004) ("An ALJ qualified and appointed pursuant to the Administrative Procedure Act acts as an independent finder of fact in conducting a hearing pursuant to section 1869 of the Act. This requires *de novo* consideration of the facts and law").

II. Principles of Law

A. Statutes and Regulations

The Medicare program, Act §§ 1801–1897, 42 U.S.C. §§ 1395–1395ccc, is administered through CMS, a component of HHS. Under the authority of section 1842(a)(1)(A) of the Act, the Department Secretary is authorized to enter into contracts with private entities for the day-to-day operations of the program.

Under the Medicare Advantage (MA) statutes, an individual entitled to Medicare Part A benefits, who is also enrolled in Medicare Part B, may elect to receive services through a Medicare Advantage Organization (MA Organization). §1851(a) of the Social Security Act, 42 U.S.C. §1395w-21(a)

The MA plans include traditional managed care plans, such as HMOs, that have participated in Medicare under Section 1876 of the Medicare Act. *Id.* The Act authorizes Medicare payment to the MA organization through contracts by which the MA organizations receive a set amount to furnish covered services to Medicare beneficiaries. Social Security Act §1853 [42 U.S.C. §1395w-23]

With limited exceptions, the MA organization must provide a Medicare enrollee all Medicare covered benefits. Social Security Act §1852(a)(1) [42 U.S.C. §1395w-22(a)(1)]; 42 C.F.R. §§422.100 and 422.101. The regulations of the Centers for Medicare and Medicaid Services

(CMS) state that the term “benefits” means health care services that are intended to maintain or improve the health status of enrollees, for which the MA organization incurs a cost or liability under an MA plan (not solely an administrative processing cost). 42 C.F.R. §422.2

As defined in the Act and regulations of the CMS, “basic benefits” are those items under Parts A and B of Medicare and “additional benefits”. Social Security Act §1852(a) [42 U.S.C. §1395w-22(a)]; 42 C.F.R. §§422.2, 422.100(c)(1), and 422.101. Additional benefits are health care services not covered by Medicare, reductions in premiums or cost-sharing for Medicare covered services, and reductions in the Medicare beneficiary’s standard Part B premium, funded from adjusted excess amounts as calculated in the adjusted community rate (ACR). Social Security Act §1854(f)(1)(A) [42 U.S.C. §1395w-24(f)(1)(A)]; 42 C.F.R. §422.2.

A Medicare beneficiary enrolled in an eligible MA plan is entitled to receive all the items and services (except hospice services) that are covered by Part A and B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B) and that are available to beneficiaries residing in the geographic area served by the organization. Social Security Act §1852(a)[42 U.S.C. §1395w-22(a)]; 42 C.F.R. §422.101. The MA organization must provide enrollees in the MA plan with these services by furnishing such benefits directly, through arrangements, or by paying for the benefits. *Id.* The MA organization must also provide its enrollees access to appropriate providers, including credentialed specialists, for medically necessary treatment and services. Social Security Act §1852(d)(1)(D) [42 U.S.C. §1395w-22(d)(1)(D)]

An MA organization is subject to federal regulations detailing disclosure requirements, as found at 42 C.F.R. §422.111.

An MA organization that offers an MA coordinated care plan may specify the networks of providers from whom enrollees may obtain services if the MA organization ensures that all covered services, including supplemental services contracted by (or on behalf of) the Medicare enrollee, are available and accessible under the plan. 42 C.F.R. §422.112(a)

An individual who enrolls in an MA plan agrees to abide by the rules of the MA organization and to obtain Medicare services from the organization. 42 C.F.R. §422.50(a)(6) As a general rule, if the enrollee obtains services or items from providers or suppliers not connected with the MA organization it is not required to reimburse the enrollee. 42 C.F.R. §417.448

An MA plan includes, at a minimum, basic benefits and also may include mandatory and optional supplemental benefits. 42 C.F.R. §422.101(c) An MA organization offering an MA plan must offer it (1) to all Medicare beneficiaries residing in the service area of the plan; 2) at a uniform premium, with uniform benefits and level of cost-sharing throughout the plan’s service area, or segment of service area. 42 C.F.R. §422.101(d)

The MA organization is also required to cover “urgently needed services”, which do not constitute emergency services, but are provided when an enrollee is temporarily absent from the MA plan’s service, or continuation area, when the services are medically necessary and immediately required. Social Security Act §1852(d)(1)(C)(i) [42 U.S.C. §1395w-22(d)(1)(C)(i)]; 42 C.F.R. §422.113(b)(1)(iii)

B. Policy and Guidance

In regard to basic benefits, each MA organization must comply with CMS' National Coverage Determinations and general coverage guidelines included in the Medicare manuals and instructions (unless superseded by operational policy letters with jurisdiction for claims in the geographic area in which services are covered under the MA organization). 42 C.F.R. §422.101(b) However, compliance with National Coverage Decisions (NCDs) does not prevent an Administrative Law Judge from deciding coverage based upon particular facts constituting adequate justification for non-compliance with Medicare regulation, as set forth in the following regulations:

42 C.F.R. §405.1062 Applicability of local coverage determinations and other policies not binding on the ALJ or attorney adjudicator and Council.

- (a) ALJs and attorney adjudicators and the Council are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.
- (b) If an ALJ or attorney adjudicator or Council declines to follow a policy in a particular case, the ALJ or attorney adjudicator or Council decision must explain the reasons why the policy was not followed. An ALJ or attorney adjudicator or Council decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.

Specific to the subject appeal, CMS has adopted the American Medical Association's International Classification of Diseases, 9th Edition (ICD-9) Codes in describing the appropriate diagnoses as rendered by a health care provider, as well as the National Comprehensive Cancer Network (NCCN) guidelines as to standards of care for glioblastoma multiforme patients.

Items and services that are not "reasonable and necessary" for the diagnosis or treatment of illness or injury of the beneficiary or to improve the functioning of a malformed member of the beneficiary's body are specifically excluded from Medicare coverage under the provisions of Section 1862 of the Act. Social Security Act §1862(a)(1)(A) [42 U.S.C. §1395y(a)(1)(A)] CMS has also adopted the Healthcare Common Procedure coding System (HCPCS), the Current Procedural Terminology (CPT) Codes, and the International Classification of Diseases, 9th Edition (ICD-9) Codes, from the American Medical Association. The codes as referenced within this section are referenced per the regulations for HCPCS, CPT, and ICD-9 codes during the period of the subject dates of service.

ANALYSIS

1. **The Medicare Advantage Organization, CIGNA Healthspring Achieve Plus SNP (the Plan) is required to approve the Optune Plus Transducer system as**

requested by the Appellant/Enrollee, [REDACTED] for which he sought pre-approval.²

The instant appeal is from a party dissatisfied with the decision of the designated Part C Independent Review Entity (IRE), Maximus Federal Services, to deny pre-approval and coverage of the Optune plus Transducer system for treatment of glioblastoma multiforme.

Maximus determined that the Medicare Advantage Organization, Healthspring Achieve Plus SNP, was found to be in compliance with Medicare's disclosure requirements as set forth within its Evidence of Coverage, disallowing coverage of the Optune system (HCPCS Code E0766) pursuant to Local Coverage Determination L34823, which characterized the Optune system as experimental, determined by the Plan and original Medicare as not to be generally accepted by the medical community.

- Attorney Deborah Parrish, Counsel for the Appellant, presented in her Opening Statement the Position of the Appellant/Enrollee: pursuant to 42 C.F.R. §405.1062, the undersigned should not follow the prohibition of pre-approval of coverage of the Optune system, as L34823 relies upon a false premise that Optune, an FDA-approved treatment for glioblastoma multiforme, is experimental, based upon sufficient evidence of medical necessity to be elaborated upon through testimony from witnesses as set forth herein:
- Christopher Dardis, M.D., a neuro oncologist and the Appellant's physician, testified that TTFT was the best effort to arrest the metastasis of the Appellant's GBM status post resection on or about May 8, 2018 of a left insular tumor as well as radiation with a concurrent course of Temozolomide;
- Rudolph Cane, M.D., Medical Director, CIGNA, stated the Position of the MAO Plan that the Optune system was not covered pursuant to the 2018 Evidence of Coverage, as CIGNA considered the subject GBM treatment as experimental.

A review of the record and the oral testimony as elicited during the ALJ Hearing of December 6, 2018, leads to the conclusion that the Appellant/Enrollee has shown sufficient proof of medical necessity for the subject Optune plus Transducer system to be recommended for approval of coverage by the Plan, CIGNA Healthspring Achieve Plus SNP. There is sufficient evidence that the Optune system, approved by prescription by his treating oncologist, was particularly tailored to his treatment history. With the progression of GBM with the presence of a tumor in the site of resection as confirmed by MRI in August 2018, and a viable alternative to a standard of care which destroys brain tissue with the use of electric field to impeded neoplastic mytosis, as well as proof of FDA approval of Optune, the undersigned hereby finds that a factual predicate exists to overcome a general prohibition of coverage of HCPCS Code E0766 pursuant to 42 C.F.R. §405.1062.

² The undersigned notes that testimony in the subject appeal was voluminous and technically complex. In fairness to the parties for each side of the issue of coverage, summaries of testimony adduced during the Administrative Law Judge Hearing of December 6, 2018, as well as pertinent testimony elicited through cross-examination, are included in the Analysis. Further, the undersigned considered the documentary evidence in the form of peer review articles on the efficacy of the Optune system; while not conclusive, they are deemed persuasive evidence in their presentation of the findings of studies of samples of GBM patients for the proposition that Optune made a significant difference in the survival rates of recurrent GBM patients.

For the reasons as set forth infra, the Appellant's request for approval and coverage of the subject Optune with Transducers system is granted: the Appellant has provided sufficient evidence of a medical need for the cancer treatment DME. CIGNA therefore was not in compliance with Medicare's requirements of access to basic benefits as set forth at disclosure requirements as set forth at 42 C.F.R. §§422.2, 422.100(c)(1), and 422.101 in its denial of coverage pursuant to L34823. The Appellant is therefore eligible for coverage of the Optune system.

CONCLUSIONS OF LAW

Based on the totality of the evidence of record, the undersigned ALJ concludes that:

The Appellant/Enrollee, [REDACTED], is entitled to approval and full coverage of the costs of the six-month rental of the Optune System, billed using HCPCS Code E0766, as the Plan, CIGNA Healthspring Achieve Plus SNP, is deemed not to be compliant with health care access requirements set forth at 42 C.F.R. §§422.2 and 422.111.

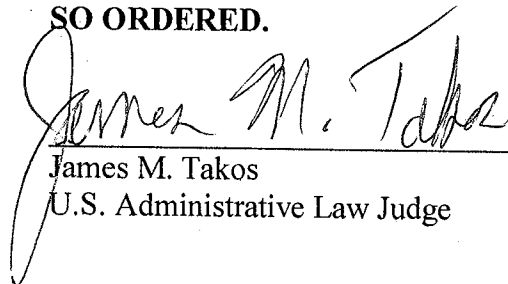
ORDER

The Medicare IRE, Maximus Federal Services, is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated:

JAN 17 2019


James M. Takos
U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Irvine, California

Appeal of:

REDACTED

OMHA Appeal No.: 1-8116489699

Beneficiary:

Medicare: Part B

Medicare No.:

Before: James M. Takos
U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, a **FULLY FAVORABLE** decision is entered for Appellant/Beneficiary, (hereinafter "Appellant")
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PROCEDURAL HISTORY

On or about March 1, 2018, Novocure, a non-Medicare contracted DME Supplier, submitted claims for three months of rental of an electrical stimulation device (Optune) and Transducer Array, the subject DME comprising Tumor Treatment Field Therapy (TTFT) used for the treatment of Glioblastoma Multiforme (GBM) (3 total units). On May 14, 2018, CGS, the assigned Part B Medicare Administrative Contractor ("MAC"), issued a Notice of Redetermination denying coverage of the subject monthly rentals. (Ex. 1, pg. 14)

On or about November 15, 2018, following a Request for Reconsideration by Novocure on behalf of the Appellant, the assigned Durable Medical Equipment Qualified Independent Contractor ("DME QIC"), C2C Innovative Solutions, Inc. ("C2C") issued a denial of coverage of the three months of Optune rental on appeal, affirming CGS' denial, the rationale given as follows: "the available documentation received indicates the Beneficiary has a diagnosis of glioblastoma [multiforme]...however, the medical documentation does not support the need for the device, which is required as outlined in [Medicare regulations]...there is insufficient documentation to quantify the effects of the device for this Beneficiary. The currently published studies in the medical literature do not clearly document the effectiveness of this device. Therefore, payment cannot be allowed." (Ex. 1, pg. 1)

The Appellant filed a timely request with the Office of Medicare and Appeals (OMHA) for a hearing before an Administrative Law Judge (ALJ) and the amount in controversy satisfies the jurisdictional requirement for this action. See 42 C.F.R. §§405.1006 and 405.104. This matter is properly before the undersigned ALJ.

Subsequent to the Appellant's request for an ALJ Hearing, and following a thorough examination of the submitted record, pursuant to 42 C.F.R. §405.1038, the undersigned determines that a Fully Favorable decision in favor of the Appellant is warranted. Therefore, the undersigned issues the subject decision On the Record, without need for an ALJ Hearing.

ISSUE

The Part B DME QIC, C2C Solutions, denied coverage of the subject three months of rental (Dates of Service of December 22, 2017, January 22, 2018, and February 22, 2018, respectively). The issue to be determined by the Administrative Law Judge (ALJ) is:

Whether the rental of the Optune Plus Transducer system was met the conditions of payment as a valid treatment option for Glioblastoma Multiforme (GBM) as requested by the Appellant, REDACTED, and was thus subject to reimbursement pursuant to §§1833 and 1834 of Title XVIII of the Social Security Act;

- i) Whether three monthly rentals of Durable Medical Equipment, namely, an Optune Plus Transducer system plus maintenance doses of Temozolomide, billed using HCPCS Code E0766, provided to the Appellant on December 22, 2017, January 22, 2018, and February 22, 2018 – are covered under Part B of the Medicare program, i.e., are they medically reasonable and necessary under Medicare pursuant to the provision of Section 1862(a)(2) of the Social Security Act?
- ii) If not, is the Appellant liable pursuant to the waiver of liability provisions of Section 1879 of the Social Security Act?

FINDINGS OF FACT

The following facts are established by a preponderance of the evidence.

1. The Appellant is a 76 year-old female (date of birth of February 8, 1942. (Ex. 2, pg. 14)
2. On or about September 12, 2017, the Appellant presented to University Cancer and Blood Center with complaint of speech difficulty and right-sided weakness. She was found to have a mass involving her brain (a diagnosis of glioblastoma multiforme) and underwent a resection by a Dr. REDACTED on September 12, 2017, with concurrent chemotherapy and radiation. (Ex. 2, pg. 2)
3. From October 12 to November 22, 2017, the Appellant underwent radiation therapy with chemotherapy with Temozolomide under the care of REDACTED Dr. REDACTED subsequently determined that at completion of radiation and chemotherapy treatments, the Optune Transducer Array would be beneficial in the mitigation of further progress of the Appellant's GBM diagnosis. (Ex. 2, pgs. 1, 19)
4. The Follow-up Visit with Dr. REDACTED recorded the imaging results for Optune therapy from February 5, 2018 to June 11, 2018, highlights pertinent to the subject appeal follow: "February 5, 2018. CT Brain. Improvement since her initial postop scan. Mass-effect and edema from the residual tumor showed markedly decreased. No new abnormality"; "April 11, 2018. MRI Brain: interval improvement with decreased size of the left

frontal., left anterior corpus callosum tumor mass, decrease in size 2 cm maximally. Increased white matter hyperintensity suggesting radiation effect”; “June 11, 2018: MRI Brain: Residual enhancing tumor in the left frontal area adjacent to the lateral ventricle with a further decrease in size, currently measuring 1.4 x 1.5 cm (prior 2 x 1.9 cm)”. (Ex. 2, pg. 12)

5. Dr. REDACTED drafted a Statement of Position in Support of coverage of the subject Optune Transducer system dated August 2, 2018. Of note: as of 2015, National Comprehensive Cancer Network (“NCCN”), Tumor Treatment Field Therapy (“TTFT”) was included in NCCN’s treatments for GBM. (Ex. 2, pg. 4)

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) §1869(b)(1)(A)

In implementing this statutory directive, the Secretary has delegated his authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *Id.*

A hearing before an ALJ is only available if the remaining amount in controversy is \$140 or more. *See* CMS Rul. 02-1, 67 Fed. Reg. 62478, 62480 (Oct. 7, 2002); 77 Fed. Reg. 58916 (September 28, 2012). The request for hearing is timely if filed within sixty days after receipt of a Carrier Hearing Officer decision. *See* 20 C.F.R. §404.933(b)(1).

B. Scope of Review

Under the Centers for Medicare and Medicaid Services’ (CMS) implementation policy for the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. Law 106-554, app. F, 114 Stat. 2763, 2763A-463, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. Law 108-173, 117 Stat. 2066, all initial determinations by CMS contracted Carriers prior to January 1, 2006, are governed by the ALJ hearing procedures set forth at 20 C.F.R. §§ 404.929 through 404.961 and 42 C.F.R. § 405.855. *See* 70 Fed. Reg. 11420, 11424-26 (Mar. 8, 2005).

“The issues before the Administrative Law Judge include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in [the Appellant’s] favor. However, if evidence presented before or during the hearing causes the Administrative Law Judge to question a fully favorable determination, he or she will notify [the Appellant] and will consider it an issue at the hearing.” 20 C.F.R. §404.946(a)

“The Administrative Law Judge may decide a case on the record and not conduct an oral hearing if [the Appellant] and all the parties indicate in writing that [they] do not wish to appear before the Administrative Law Judge at an oral hearing.” 20 C.F.R. § 404.948(b)(i)

C. Standard of Review

“The [Office of Medicare Hearings and Appeals]...is staff[ed] with Administrative Law Judges who conduct ‘de novo’ hearings....” 70 Fed. Reg. 36386 (June 23, 2005); *see also In re Atlantic Anesthesia Associates, P.C.*, MAC (June 2004) (“An ALJ qualified and appointed pursuant to the Administrative Procedure Act acts as an independent finder of fact in conducting a hearing pursuant to section 1869 of the Act. This requires *de novo* consideration of the facts and law”).

II. Principles of Law

A. Statutes and Regulations

Title XVIII of the Act, as amended (42 U.S.C. §1395 *et seq.*), establishes a federally subsidized health insurance program (“Medicare”) to be administered by the Department of Health and Human Services. Eligibility for Medicare benefits is determined under Title XVIII of the Act and the federal regulations set forth in Title 42 of the Code of Federal Regulations (“C.F.R.”).

Section 1831 of the Social Security Act (the Act) establishes the supplemental medical insurance benefit program (Medicare Part B). Section 1832 of the Act describes the scope of the benefits provided by Medicare Part B. Sections 1832(a)(1), 1832(a)(2)(B), 1832(a)(2)(G), 1834(a)(13), 1861(n) and 1861(s)(6) of the Act and Regulations of the Centers for Medicare and Medicaid Services (CMS) provide that Medicare Part B benefits include payment for medical supplies (42 C.F.R. §410.3).

Section 1834(a)(11) (B) of the Act and CMS Regulations provide that a written physician order may be required by a supplier before delivery of medical supplies (42 C.F.R. §410.36(b)). Section 1835(a)(2)(B) of the Act and CMS Regulations provide that for services and supplies provided by a provider of services, a physician must certify the medical necessity of the item in writing (42 C.F.R. §§424.24(b) and 424.24(f)).

Section 1834(j)(1) of the Act requires suppliers of medical equipment and supplies to obtain a supplier number and meet certain criteria, including complying with Federal and State licensure requirements, having an appropriate facility on an appropriate site and having appropriate liability insurance.

Section 1833(e) of the Act and CMS Regulations provide that claims for payment must be supported by sufficient information and documentation. (42 C.F.R. §424.5(a)(6)) Furthermore, guidance is found in the Medicare Program Integrity Manual, Chapter 5, Section 5.7, which states that the documentation in the patient’s medical record does not have to be routinely sent to the supplier or to the Durable Medical Equipment Medicare Administrative Contractors (DME MACs), DME Program Safeguard Contractor (PSCs), or Zoned Program integrity Contractors (ZPICs). However, the DME MACs, DME PSCs, or ZPICs may request the information in selected cases. If the DME, DME PSCs, or ZPICs do not receive the information when requested or if the information in the patient’s medical record does not adequately support the medical necessity of the item, then on assigned claims the supplier is liable for the dollar amount

involved unless a properly executed advance beneficiary notice (ABN) of possible denial has been obtained.

Section 1862(a)(1)(A) of the Act and CMS Regulations exclude from Medicare coverage and payment items and services that are not medically reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. (42 C.F.R. §411.15(k))

Section 1879 of the Act provides that when Medicare coverage and payment is excluded pursuant to Section 1862(a) (1) of the Act, payment may nevertheless be made for items or services, if neither the beneficiary nor the provider or supplier knew, and could not reasonably be expected to have known, that the items or services would not be covered or payable by Medicare. CMS Regulations provide that a provider or supplier will be considered to have known that items or services would not be covered or payable by Medicare if they are given direct notice of this by CMS or any of its agents, including intermediaries and Carriers, by utilization review committees, or by the beneficiary's attending physician. (42 C.F.R. §§411.406(b) and (c))

A provider or supplier is also considered to have notice that services are not covered if they inform the beneficiary that the services are not covered by Medicare (42 C.F.R. §411.406(d)). A provider or supplier is also considered to have notice that services are not covered if it is clear that they could have been expected to know that from their receipt of notices from CMS or its agents, publication in the Federal Register, or based on their "knowledge of what are considered acceptable standards of practice by the local medical community". (42 C.F.R. §411.406(e))

B. Policy and Guidance

In regard to basic benefits, each MA organization must comply with CMS' National Coverage Determinations and general coverage guidelines included in the Medicare manuals and instructions (unless superseded by operational policy letters with jurisdiction for claims in the geographic area in which services are covered under the MA organization). 42 C.F.R. §422.101(b) However, compliance with National Coverage Decisions (NCDs) does not prevent an Administrative Law Judge from deciding coverage based upon particular facts constituting adequate justification for non-compliance with Medicare regulation, as set forth in the following regulations:

42 C.F.R. §405.1062 Applicability of local coverage determinations and other policies not binding on the ALJ or attorney adjudicator and Council.

(a) ALJs and attorney adjudicators and the Council are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.

(b) If an ALJ or attorney adjudicator or Council declines to follow a policy in a particular case, the ALJ or attorney adjudicator or Council decision must explain the reasons why the policy was not followed. An ALJ or attorney adjudicator or Council decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.

Specific to the subject appeal, CMS has adopted the American Medical Association's International Classification of Diseases, 9th Edition (ICD-9) Codes in describing the appropriate diagnoses as rendered by a health care provider, as well as the National Comprehensive Cancer Network (NCCN) guidelines as to standards of care for glioblastoma multiforme patients.

Items and services that are not "reasonable and necessary" for the diagnosis or treatment of illness or injury of the beneficiary or to improve the functioning of a malformed member of the beneficiary's body are specifically excluded from Medicare coverage under the provisions of Section 1862 of the Act. Social Security Act §1862(a)(1)(A) [42 U.S.C. §1395y(a)(1)(A)] CMS has also adopted the Healthcare Common Procedure coding System (HCPCS), the Current Procedural Terminology (CPT) Codes, and the International Classification of Diseases, 9th Edition (ICD-9) Codes, from the American Medical Association. The codes as referenced within this section are referenced per the regulations for HCPCS, CPT, and ICD-9 codes during the period of the subject dates of service.

Additionally, Local Coverage Determination L34823 sets forth further coverage guidelines with respect to the Optune Transducer Array:

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act §1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity: Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary."

ANALYSIS

- 1. The Appellant, REDACTED, is eligible for coverage of the Optune Transducer System, as the treatment is supported by the evidence presented as being medically reasonable and necessary.**

The instant appeal is from a party dissatisfied with the decision of the designated Part B DME QIC, C2C Solutions, to deny coverage of the Optune Plus Transducer System with Temozolomide for treatment of glioblastoma multiforme.

C2C determined that the Optune Transducer System as prescribed to the Appellant was not eligible for coverage; specifically, Medicare regulation as set forth in Local Coverage Determination L34823 disallowing coverage of the Optune system (HCPCS Code E0766), which characterized the Optune system as experimental, determined by original Medicare as not to be generally accepted by the medical community.

- Attorney Deborah Parrish, Counsel for the Appellant and her Representative in the subject appeal, presented in her Pre-Hearing Brief dated December 3, 2018 the following in support of coverage: Optune is FDA-approved for recurrent and newly-diagnosed GCM brain tumors. On January 1, 2014, CMS classified the Optune device as DME requiring frequent and substantial servicing, which is billed under HCPCS Code E0766 as a monthly rental through the duration of medical necessity.

A review of the record leads to the conclusion that there exists sufficient evidence of medical necessity to allow a recommendation for the subject Optune plus Transducer system for coverage by Medicare Part B. The Follow-up Notes from several months of Optune treatment following

its prescription by the Appellant's oncologist, Dr. REDACTED in December 2017, specifically, treatment from February to June 2018, demonstrated reduction in size of cancerous masses in the brain. There is sufficient evidence that the Optune system, approved by prescription by her treating oncologist, was particularly tailored to her treatment history. With the likelihood progression of GBM with the presence of a tumor in the site of resection, and a viable alternative to a standard of care which destroys brain tissue with the use of electric field to impeded neoplastic mytosis, as well as proof of FDA approval of Optune, the undersigned hereby finds that a factual predicate exists to overcome a general prohibition of coverage of HCPCS Code E0766 pursuant to 42 C.F.R. §405.1062.

For the reasons as set forth infra, the Appellant's request for approval and coverage of the subject Optune with Temozolomide is granted: the Appellant has provided sufficient evidence of a medical need for the cancer treatment DME. The Reconsideration findings of C2C are therefore set aside: the Appellant is not liable for the three monthly rental payments for which the Appellant seeks coverage under Part B of the Medicare program, as the treatment is medically reasonable and necessary under Medicare pursuant to the provision of Section 1862(a)(2) of the Social Security Act.

CONCLUSIONS OF LAW

Based on the totality of the evidence of record, the undersigned ALJ concludes that:

The Appellant, REDACTED ED is entitled to approval and full coverage of the costs of three monthly rentals of the Optune System, billed using HCPCS Code E0766, as the treatments for which the Appellant seeks coverage under Part B of the Medicare program are medically reasonable and necessary under Medicare pursuant to the provision of Section 1862(a)(2) of the Social Security Act.

ORDER

The Medicare Part B DME QIC, C2C Solutions, is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated:

JAN 16 2019


James M. Takos

U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Irvine, California

Appeal of:	OMHA Appeal No.: 1-7469945251
Enrollee:	Medicare: Part C
HICN:	Before: James M. Takos U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, a **FULLY FAVORABLE** decision is entered for Appellant/Enrollee,

PROCEDURAL HISTORY

On or about March 9, 2018, Novocure, a non-Medicare contracted DME Supplier, on behalf of the Appellant/Enrollee, requested pre-approval from Blue Cross Blue Shield of Michigan ("BCBS"), the Medicare Advantage Organization (MAO) of which the Appellant is an Enrollee, for an electrical stimulation device (Optune) and Transducer Array, the subject DME comprising Tumor Treatment Field Therapy (TTFT) used for the treatment of Glioblastoma Multiforme (GBM) as a 6-month rental (6 total units). On March 9, 2018, BCBS issued a denial of the organization determination for Optune and Transducer Arrays, indicating that their medical director determined that the requested items were not approvable as the items were not covered by Medicare. On March 23, 2018, BCBS received an appeal request from Novocure on behalf of the Appellant/Enrollee. On March 26, 2018, BCBS reiterated its denial, stating that based upon Local Coverage Determination for TTFT (L34823), TTFT (HCPCS Code E0766) will be denied as not medically reasonable and necessary, as it constituted an experimental medical/surgical procedure. (Ex. 1, pg. 10)

On or about March 27, 2018, following a Request for Reconsideration by Novocure, the assigned Independent Review Entity (IRE), Maximus Federal Services ("Maximus") issued a denial of pre-approval of the Optune system, affirming BCBS' denial with the following as its rationale: "The services at issue are Optune TTFT. These services are denied as not reasonable and necessary by Medicare for all conditions. Therefore, BCBS does not have to pre-approve an Optune TTFT for ". (Ex. 1, pg. 5)

The Appellant filed a timely request with the Office of Medicare and Appeals (OMHA) for a hearing before an Administrative Law Judge (ALJ) and the amount in controversy satisfies the jurisdictional requirement for this action. See 42 C.F.R. §§405.1006 and 405.104. This matter is

properly before the undersigned ALJ. Pursuant to a written notice, a telephonic hearing was held on June 26, 2018, at the Office of Medicare Hearings and Appeals, Irvine Field Office, Irvine, California. The Appellant/Enrollee, _____, appeared and provided testimony on her own behalf, but was further represented by the following Party participants: Attorney Stephanie Hales of Sidley Austin, LLP, representing Novocure in its request for pre-approval of Optune; Ms. Tanya Lane, Case Management Team Lead, Novocure; Amir Lavaf, M.D., the Appellant/Enrollee's Treating Physician; Justin Kelly, Senior Director for Health Policy, Novocure; and _____, niece of Appellant/Enrollee who provided testimony in support of the Appellant/Enrollee's position. The MAO Plan, Blue Cross Blue Shield of Michigan, through its Representatives, Cierra Pilson, Grievance and Appeals Coordinator, and Angela Whetstone, Team Lead, Grievance Dept., appeared and provided testimony in support of denial of the Optune TTFT system. Finally, Judy Schmidt, M.D., a Board-Certified Oncologist appointed by OMHA, provided expert testimony as to the efficacy of the Optune TTFT system. No appearance was made by the assigned Part C IRE, Maximus Federal Services. All Exhibits were admitted into the record without objection at the time of the ALJ Hearing. The record was closed and the matter was taken under submission for a decision. (Hearing CD)

ISSUES

The Part C Independent Review Entity (IRE), Maximus Federal Services, concluded that the Medicare Advantage Organization, Blue Cross Blue Shield of Michigan ("BCBS"), was justified in its denial of pre-approval of coverage of the Optune TTFT system, as requested by the Appellant/Enrollee. The issue to be determined by the Administrative Law Judge (ALJ) is:

Whether the pre-approval of rental of the Optune Plus Transducer system was met the conditions of payment as a valid treatment option for Glioblastoma Multiforme (GBM) within the context of an in-network exception as requested by the Appellant/Enrollee, _____ and was thus subject to reimbursement pursuant to §§1851-1859 (Medicare Part C) of Title XVIII of the Social Security Act;

- i) Whether the respondent Medicare Advantage Organization, BCBS, was compliant with Medicare's requirements of access to Part A and B benefits, and disclosure requirements with respect to costs billed by the Appellant for DME supplies to include the subject Optune system pursuant to 42 C.F.R. §§422.2 and 422.111;
- ii) If BCBS was not compliant with Medicare's access to Medicare benefits and disclosure requirements, whether the Appellant is eligible for pre-approval of previously-denied coverage of the subject Optune system.

FINDINGS OF FACT

The following facts are established by a preponderance of the evidence.

1. The Appellant/Enrollee is a 71 year-old female (date of birth of January 27, 1947) enrolled with Blue Cross Blue Shield of Michigan ("BCBS"). (Ex. 1, pg. 51)
2. On or about October 25, 2016, the Appellant/Enrollee presented to Emergent Care at Royal Oak Hospital with complaint of headache and left visual field cuts. A year

subsequent, in October 2017, the Appellant/Enrollee, a winter resident of Palm Springs, CA, presented to the Comprehensive Cancer Center, Palm Springs, CA, in October 2017 with complaint of a new left hemianopsia. An MRI brain revealed symptoms consistent with a diagnosis of Glioblastoma Multiforme of the right occipital lobe. The Appellant underwent surgical resection at Royal Oak Hospital on November 9, 2017, followed postoperatively with combined radiation and Temodar (chemotherapy) treatment which she completed on January 31, 2018. (Ex. 4, pg. 33)

3. On February 26, 2018, an MRI of the brain was ordered by Amir Lavaf, M.D., a Radiation Oncologist affiliated with Comprehensive Cancer Center to compare with the October 2017 MRI. The February 27, 2018 MRI revealed status post right posterior parietal craniotomy 2.4 cm lobulated rim-enhancing mass (a new tumor) at the craniotomy site. Findings were determined to be compatible with progression of GBM. (Ex. 4, pg. 16)
4. A Plan of Care was drafted by Dr. Lavaf at or near March 12, 2018, with a second cycle of high-dose Temodar to be initiated on March 29, 2018, the Appellant/Enrollee tolerating a cycle of high-dose Temodar accompanying radiation treatment which was completed at or near March 12, 2018. The record states that the cycles of radiation and Temodar are the standard of care for recurring GBM patients. (Ex. 4, pg. 12)
5. The record further contains the Optune prescription Form as drafted by Dr. Lavaf on March 19, 2018, as well a letter in support of Expedited Review of Denial to BCBS dated March 22, 2018. The Letter in Support of Pre-Approval of March 22, 2018 stated that Optune was the best course of treatment given the aggressive nature of GBM, and the limited treatment options in a recurrent GBM patient such as the Appellant/Enrollee. (Ex. 4, pgs. 8, 27)
6. Finally, the record contains BCBS' Evidence of Coverage for 2018. The EOC states that the Plan must cover all services covered by original Medicare's Coverage rules, as well as the Plan's limitations or exclusions of coverage to include: experimental medical and surgical supplies (those determined by the Plan and original Medicare to not be generally accepted by the medical community. (Ex. 1, pg. 11)

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) §1869(b)(1)(A)

In implementing this statutory directive, the Secretary has delegated his authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. See 70 Fed.

Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *Id.*

A hearing before an ALJ is only available if the remaining amount in controversy is \$140 or more. *See* CMS Rul. 02-1, 67 Fed. Reg. 62478, 62480 (Oct. 7, 2002); 77 Fed. Reg. 58916 (September 28, 2012). The request for hearing is timely if filed within sixty days after receipt of a Carrier Hearing Officer decision. *See* 20 C.F.R. §404.933(b)(1).

B. Scope of Review

Under the Centers for Medicare and Medicaid Services' (CMS) implementation policy for the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. Law 106-554, app. F, 114 Stat. 2763, 2763A-463, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. Law 108-173, 117 Stat. 2066, all initial determinations by CMS contracted Carriers prior to January 1, 2006, are governed by the ALJ hearing procedures set forth at 20 C.F.R. §§ 404.929 through 404.961 and 42 C.F.R. § 405.855. *See* 70 Fed. Reg. 11420, 11424-26 (Mar. 8, 2005).

"The issues before the Administrative Law Judge include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in [the Appellant's] favor. However, if evidence presented before or during the hearing causes the Administrative Law Judge to question a fully favorable determination, he or she will notify [the Appellant] and will consider it an issue at the hearing." 20 C.F.R. §404.946(a)

"The Administrative Law Judge may decide a case on the record and not conduct an oral hearing if [the Appellant] and all the parties indicate in writing that [they] do not wish to appear before the Administrative Law Judge at an oral hearing." 20 C.F.R. § 404.948(b)(i)

C. Standard of Review

"The [Office of Medicare Hearings and Appeals]...is staff[ed] with Administrative Law Judges who conduct 'de novo' hearings...." 70 Fed. Reg. 36386 (June 23, 2005); *see also In re Atlantic Anesthesia Associates, P.C.*, MAC (June 2004) ("An ALJ qualified and appointed pursuant to the Administrative Procedure Act acts as an independent finder of fact in conducting a hearing pursuant to section 1869 of the Act. This requires *de novo* consideration of the facts and law").

II. Principles of Law

A. Statutes and Regulations

The Medicare program, Act §§ 1801–1897, 42 U.S.C. §§ 1395–1395ccc, is administered through CMS, a component of HHS. Under the authority of section 1842(a)(1)(A) of the Act, the Department Secretary is authorized to enter into contracts with private entities for the day-to-day operations of the program.

Under the Medicare Advantage (MA) statutes, an individual entitled to Medicare Part A benefits, who is also enrolled in Medicare Part B, may elect to receive services through a Medicare Advantage Organization (MA Organization). §1851(a) of the Social Security Act, 42 U.S.C. §1395w-21(a)

The MA plans include traditional managed care plans, such as HMOs, that have participated in Medicare under Section 1876 of the Medicare Act. *Id.* The Act authorizes Medicare payment to the MA organization through contracts by which the MA organizations receive a set amount to furnish covered services to Medicare beneficiaries. Social Security Act §1853 [42 U.S.C. §1395w-23]

With limited exceptions, the MA organization must provide a Medicare enrollee all Medicare covered benefits. Social Security Act §1852(a)(1) [42 U.S.C. §1395w-22(a)(1)]; 42 C.F.R. §§422.100 and 422.101. The regulations of the Centers for Medicare and Medicaid Services (CMS) state that the term “benefits” means health care services that are intended to maintain or improve the health status of enrollees, for which the MA organization incurs a cost or liability under an MA plan (not solely an administrative processing cost). 42 C.F.R. §422.2

As defined in the Act and regulations of the CMS, “basic benefits” are those items under Parts A and B of Medicare and “additional benefits”. Social Security Act §1852(a) [42 U.S.C. §1395w-22(a)]; 42 C.F.R. §§422.2, 422.100(c)(1), and 422.101. Additional benefits are health care services not covered by Medicare, reductions in premiums or cost-sharing for Medicare covered services, and reductions in the Medicare beneficiary’s standard Part B premium, funded from adjusted excess amounts as calculated in the adjusted community rate (ACR). Social Security Act §1854(f)(1)(A) [42 U.S.C. §1395w-24(f)(1)(A)]; 42 C.F.R. §422.2.

A Medicare beneficiary enrolled in an eligible MA plan is entitled to receive all the items and services (except hospice services) that are covered by Part A and B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B) and that are available to beneficiaries residing in the geographic area served by the organization. Social Security Act §1852(a) [42 U.S.C. §1395w-22(a)]; 42 C.F.R. §422.101. The MA organization must provide enrollees in the MA plan with these services by furnishing such benefits directly, through arrangements, or by paying for the benefits. *Id.* The MA organization must also provide its enrollees access to appropriate providers, including credentialed specialists, for medically necessary treatment and services. Social Security Act §1852(d)(1)(D) [42 U.S.C. §1395w-22(d)(1)(D)]

An MA organization is subject to federal regulations detailing disclosure requirements, as found at 42 C.F.R. §422.111.

An MA organization that offers an MA coordinated care plan may specify the networks of providers from whom enrollees may obtain services if the MA organization ensures that all covered services, including supplemental services contracted by (or on behalf of) the Medicare enrollee, are available and accessible under the plan. 42 C.F.R. §422.112(a)

An individual who enrolls in an MA plan agrees to abide by the rules of the MA organization and to obtain Medicare services from the organization 42 C.F.R. §422.50(a)(6). As a general rule, if the enrollee obtains services or items from providers or suppliers not connected with the MA organization it is not required to reimburse the enrollee. 42 C.F.R. §417.448

An MA plan includes, at a minimum, basic benefits and also may include mandatory and optional supplemental benefits. 42 C.F.R. §422.101(c). An MA organization offering an MA plan must offer it (1) to all Medicare beneficiaries residing in the service area of the plan; 2) at a

uniform premium, with uniform benefits and level of cost-sharing throughout the plan's service area, or segment of service area. 42 C.F.R. §422.101(d)

The MA organization is also required to cover "urgently needed services", which do not constitute emergency services, but are provided when an enrollee is temporarily absent from the MA plan's service, or continuation area, when the services are medically necessary and immediately required. Social Security Act §1852(d)(1)(C)(i) [42 U.S.C. §1395w-22(d)(1)(C)(i); 42 C.F.R. §422.113(b)(1)(iii)]

B. Policy and Guidance

In regard to basic benefits, each MA organization must comply with CMS' National Coverage Determinations and general coverage guidelines included in the Medicare manuals and instructions (unless superseded by operational policy letters with jurisdiction for claims in the geographic area in which services are covered under the MA organization). 42 C.F.R. §422.101(b) However, compliance with National Coverage Decisions (NCDs) does not prevent an Administrative Law Judge from deciding coverage based upon particular facts constituting adequate justification for non-compliance with Medicare regulation, as set forth in the following regulations:

42 C.F.R. §405.1062 Applicability of local coverage determinations and other policies not binding on the ALJ or attorney adjudicator and Council.

(a) ALJs and attorney adjudicators and the Council are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.

(b) If an ALJ or attorney adjudicator or Council declines to follow a policy in a particular case, the ALJ or attorney adjudicator or Council decision must explain the reasons why the policy was not followed. An ALJ or attorney adjudicator or Council decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.

Specific to the subject appeal, CMS has adopted the American Medical Association's International Classification of Diseases, 9th Edition (ICD-9) Codes in describing the appropriate diagnoses as rendered by a health care provider, as well as the National Comprehensive Cancer Network (NCCN) guidelines as to standards of care for glioblastoma multiforme patients.

Items and services that are not "reasonable and necessary" for the diagnosis or treatment of illness or injury of the beneficiary or to improve the functioning of a malformed member of the beneficiary's body are specifically excluded from Medicare coverage under the provisions of Section 1862 of the Act. Social Security Act §1862(a)(1)(A) [42 U.S.C. §1395y(a)(1)(A)] CMS has also adopted the Healthcare Common Procedure coding System (HCPCS), the Current Procedural Terminology (CPT) Codes, and the International Classification of Diseases, 9th Edition (ICD-9) Codes, from the American Medical Association. The codes as referenced within this section are referenced per the regulations for HCPCS, CPT, and ICD-9 codes during the period of the subject dates of service.

ANALYSIS

- 1. The Medicare Advantage Organization, Blue Cross Blue Shield of Michigan PPO (the Plan) is required to approve the Optune plus Transducer system as requested by the Appellant/Enrollee, for which she sought pre-approval.¹**

The instant appeal is from a party dissatisfied with the decision of the designated Part C Independent Review Entity (IRE), Maximus Federal Services, to deny pre-approval and coverage of the Optune plus Transducer system for treatment of glioblastoma multiforme.

Maximus determined that the Medicare Advantage Organization, Blue Cross Blue Shield of Michigan, was found to be in compliance with Medicare's disclosure requirements as set forth within its Evidence of Coverage, disallowing coverage of the Optune system (HCPCS Code E0766) pursuant to Local Coverage Determination L34823, which characterized the Optune system as experimental, determined by the Plan and original Medicare as not to be generally accepted by the medical community.

- Attorney Stephanie Hales, Counsel for Novocure, presented in her Opening Statement the Position of Novocure on behalf of the Appellant/Enrollee: pursuant to 42 C.F.R. §405.1062, the undersigned should not follow the prohibition of approval of coverage of the Optune system, as L34823 relies upon a false premise that Optune, an FDA-approved treatment for glioblastoma multiforme, is experimental, based upon sufficient evidence of medical necessity to be elaborated upon through testimony from witnesses as set forth herein:
- Amir Lavaf, M.D., a Radiation Oncologist affiliated with Comprehensive Cancer Center of Palm Springs, California, and the Appellant/Enrollee's Treating Physician from January to March 2018, provided testimony in support of Optune coverage on the behalf of [redacted] which is summarized as follows: following an MRI which was conducted in February 2017 to compare with a previous MRI conducted in October 2017 which originally detected [redacted] GBM, Dr. Lavaf detected a new tumor at the site of the original resection. This tumor suggested progression of GBM, and Dr. Lavaf, following consultation with [redacted] presented the option of Optune in lieu of further radiation and Temodar cycles of treatment mid-March 2018. Dr. Lavaf testified that Ms. [redacted] made the optimal candidate for Optune, as she did not present significant neurological deficits, and had a willing and able caregiver to help her with the TTFT apparatus. He further testified that in his professional medical opinion, Optune had shown good results in patients with recurrent GBM, and that prior to TTFT, there were no patients to his knowledge that had a survival rate of 2 years or more. Dr. Lavaf did not contemplate re-section in his consultation with [redacted] March 2018, and

¹ The undersigned notes that testimony in the subject appeal was voluminous and technically complex. In fairness to the parties for each side of the issue of coverage, summaries of testimony adduced during the Administrative Law Judge Hearing of June 26, 2018, as well as pertinent testimony elicited through cross-examination, are included in the Analysis. Further, the undersigned considered the documentary evidence in the form of peer review articles on the efficacy of the Optune system; while not conclusive, they are deemed persuasive evidence in their presentation of the findings of studies of samples of GBM patients for the proposition that Optune made a significant difference in the survival rates of recurrent GBM patients.

further admitted that no neurosurgeon had reviewed the MRI as conducted in February 2018. He had no knowledge of furtherance of progression of the Appellant/Enrollee's GBM post-March 2018, as the Appellant had returned to Michigan following his prescription and treatment plan being drafted in mid-March 2018;

- Mr. Justin Kelly, Senior Health Policy Director for Novocure, provided testimony as to the results of clinical trials of Optune compared to the GBM standard of care of combinations of chemotherapy and radiation. He stated that clinical trials focusing on overall survival of GBM patients administered Optune showed a significant difference in outcomes for those patients administered Optune, with survival rate and quality of life showing an improvement over conventional oncological protocol for GBM. Mr. Kelly further testified as to the physics pertaining to the application of an electric field to the scalp of the patient through Transducer arrays with the goal of arresting mytosis of neoplastic cells in the brain without causing further tissue damage;
- , niece of the Appellant, provided clarifying testimony that the Appellant/Enrollee upon return to Michigan after March 2018 provided her February 2018 MRI to neurosurgeons at Royal Oak Hospital who confirmed progression of her GBM, but did not recommend resection. Further, chemotherapy was not continued, as had suffered a fall, which precluded chemotherapy: hence the urgency of her request for approval of the Optune system;
- The position of BCBS of Michigan as presented by Ms. Cierra Pilson was essentially as follows: the Plan's Evidence of Coverage of 2018 was clear in its prohibition of coverage of Optune, as it did not constitute original Medicare's standard of care, and was deemed experimental;
- Finally, the undersigned incorporates by reference the entire report of Judy Schmidt, M.D., the OMHA-appointed medical oncology expert (Ex. 5, pgs. 21-22). Additionally, the essence of Dr. Schmidt's opinion as to Optune's efficacy was as follows: Dr. Schmidt did not concur with a continued course of treatment of adjuvant chemotherapy with Temodar commencing March 5, 2018, as the Appellant/Enrollee's GBM had progressed on Temodar and had not presented with any disease free interval (three months per her testimony). As to the question of the efficacy of the Optune system in a patient with recurrent GBM as a viable alternative, Dr. Schmidt testified that the treatment was not the "best" treatment option, per NCCN guidelines, as chemotherapy continued to be considered a viable option for recurrent GBM, only a viable option.

A review of the record and the oral testimony as elicited during the ALJ Hearing of July 26, 2018, leads to the conclusion that the Appellant/Enrollee has shown sufficient proof of medical necessity for the subject Optune plus Transducer system to be recommended for approval of coverage by the Plan, Blue Cross Blue Shield of Michigan. There is sufficient evidence that the Optune system, approved by prescription by her treating oncologist, was particularly tailored to her treatment history. With the progression of GBM with the presence of a tumor in the site of resection as confirmed by MRI in February 2018, and a viable alternative to a standard of care which destroys brain tissue with the use of electric field to impeded neoplastic mytosis, as well as proof of FDA approval of Optune, the undersigned hereby finds that a factual predicate exists to overcome a general prohibition of coverage of HCPCS Code E0766 pursuant

to 42 C.F.R. §405.1062.

For the reasons as set forth infra, the Appellant's request for approval and coverage of the subject Optune with Transducers system is granted: the Appellant has provided sufficient evidence of a medical need for the cancer treatment DME. BCBS therefore was not in compliance with Medicare's requirements of access to basic benefits as set forth at disclosure requirements as set forth at 42 C.F.R. §§422.2, 422.100(c)(1), and 422.101 in its denial of coverage pursuant to L34823. The Appellant is therefore eligible for coverage of the Optune system.

CONCLUSIONS OF LAW

Based on the totality of the evidence of record, the undersigned ALJ concludes that:

The Appellant/Enrollee, DC, is entitled to approval and full coverage of the costs of monthly rental of the Optune System, billed using HCPCS Code E0766, as the Plan, Blue Cross Blue Shield of Michigan, is deemed not to be compliant with health care access requirements set forth at 42 C.F.R. §§422.2 and 422.111.

ORDER

The Medicare IRE, Maximus Federal Services, is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated:

JUL 26 2018



James M. Takos
U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Miami, Florida

Appeal of:

OMHA Appeal No.: 1-7832129359

Beneficiary:

Medicare: **Part B**

Medicare No.:

Before: **Scott Tews**
U.S. Administrative Law Judge

DECISION

After carefully considering the arguments and evidence presented in the record, a **FULLY FAVORABLE** decision is entered in the appeal of (Appellant/Beneficiary).

Procedural History

A claim was submitted seeking Medicare coverage and payment for an E0766 (electrical stimulation device used for cancer treatment) furnished to the Appellant on August 23, 2017, September 23, 2017, October 23, 2017 and November 23, 2017 (dates of service) by Novocure (Provider/Supplier). Medicare coverage was denied at the initial determination and redetermination levels by Noridian Healthcare Solutions, the Medicare Administrative Contractor (Contractor). (Exh. 1) The Appellant requested reconsideration and on July 11, 2018, C2C Innovative Solutions, Inc., the Medicare Qualified Independent Contractor (QIC) upheld the prior denials. (*Id.*) The QIC denied coverage on the basis that there was insufficient documentation to quantify the effects of the device for this beneficiary and no additional medical records have been submitted to explain why this particular beneficiary should be considered for this treatment. (*Id.*) Additionally, the QIC added that no documentation had been received to show the suggested manufacturer retail price for the service(s) billed. (*Id.*) The QIC held Novocure liable for the denied charges. (*Id.*)

The Appellant requested an Administrative Law Judge (ALJ) hearing, which was received by the Office of Medicare Hearings and Appeals (OMHA) on August 24, 2018. (Exh. 3) Along with the request for an ALJ hearing, an Appointment of Representative form was submitted designating Debra M. Parrish, Esq. as counsel for the Appellant. (*Id.*) The hearing request was timely filed and the amount in controversy satisfies the jurisdictional requirement for an ALJ hearing pursuant to Title XVIII of the Social Security Act (Act) § 1869(b)(1)(E). (Exh. 1; Exh. 3)

In correspondence directed to the undersigned, Attorney Parrish requested pending dates of service be aggregated to this appeal. Dates included December 23, 2017, January 23, 2018 and

February 23, 2018. Upon review, the undersigned has determined that these requested dates cannot be added to the dates of service in this current appeal.

On November 26, 2018, the undersigned ALJ held a telephonic hearing from the OMHA Miami Field Office. The QIC was provided with a notice of hearing, but did not attend. Attendees at the hearing included: Debra Parrish, Counsel for the Appellant and Julie Miles. The Appellant's representative submitted a pre-hearing brief with additional evidence to the undersigned. The additional evidence has been admitted into the record as Exhibit 5¹. The record includes Exhibits one (1) through five (5), which were admitted without objection and the recorded hearing testimony.

Issues

Whether Medicare coverage exists for the E0766 (electrical stimulation device used for cancer treatment) provided to the Appellant on August 23, 2017, September 23, 2017, October 23, 2017 and November 23, 2017, and, if not, who is responsible for the non-covered charges?

Findings of Fact

The Appellant, a then 70 year old male female was diagnosed with a left precentral gyrus glioblastoma²(GBM) (WHO grade IV) in May 2017. (Exh. 2, p. 26; Exh. 5) Prior to her diagnosis, the Appellant was experiencing expressive aphasia and slurred speech. (Exh. 2, p. 26) Upon presentation to the hospital, an MRI revealed an enhancing necrotic mass at the left post central gyrus. (*Id.*) On May 30, 2017 the Appellant underwent a left frontal craniotomy with subtotal resection with pathology showing glioblastoma. (*Id.*) Following surgery, her clinician prescribed chemoradiation therapy and the Optune System. (Exh. 5; Exh. 2, pp. 5-6) The record reflects the Appellant underwent the prescribed treatment. (Exh. 2; Exh. 5) The Appellant's most recent MRI contained in the record dated March 27, 2018 showed stable findings compared to her previous scans. (Exh. 5) Progress notes confirm the Appellant remained clinically and radiographically stable and was advised to continue monthly Temozolomide³ and Optune. (*Id.*) She was tolerating the Optune system well. (*Id.*)

At the lower levels, the Appellant submitted a letter to Contractor dated August 31, 2017 indicating that TTF was the Appellant's best option to treat her fatal disease. (Exh. 1, pp. 15-16) The Appellant noted that she began using Optune on August 23, 2017 and has been optimistic about its outcome. (*Id.*) The Appellant further noted that the Optune device is covered by numerous local and national insurance carriers and emphasized that alternating electric field therapy (Optune) + adjuvant temozolomide is now an NCCN Category 2A recommendation following postoperative standard brain radiation therapy with concurrent temozolomide. (*Id.*)

¹ The evidence submitted by the Appellant's representative has been admitted into the record pursuant to 42 C.F.R. § 405.1018(d)(2).

² **Glioblastoma (GBM)** is an aggressive type of cancer that can occur in the brain or spinal cord. GBM tumors form from cells called astrocytes that support nerve cells. GBM can occur at any age but tends to occur more often in older adults, and can cause worsening headaches, nausea, vomiting and seizures. GBM, also known as glioblastoma multiforme, can be very difficult to treat and a cure is often not possible. Treatments may slow progression of the cancer and reduce signs and symptoms (See Mayo Clinic at <https://www.mayoclinic.org/diseases-conditions/glioblastoma/cdc-20350148>).

³ **Temozolomide** (brand name: **Temodar**) is a chemotherapy drug used to treat GBM (See Chemocare at <http://chemocare.com/chemotherapy/drug-info/Temozolomide.aspx>).

The record contains an Optune Prescription Form dated June 29, 2017 prescribing 6 months of Optune for the Appellant due to malignant neoplasm of overlapping sites of brain (C71.8). (Exh. 2, pp. 5-6) The prescription preferred treatment start date was August 20, 2017. (*Id.*) Novocure issued invoices for the NOVO-TTF 100A in the amount of \$21,000 for each month dated August 23, 2017, September 23, 2017, October 23, 2017 and November 23, 2017. (Exh. 2, pp. 1-4) The Optune Service Agreement and delivery confirmation was signed by the Appellant on August 23, 2017. (Exh. 2, pp. 11-22) The Appellant also signed off on the patient information and consent. (Exh. 2, pp. 23-25)

The record contains a letter from Joel E. Kaiser Director of the Division of DMEPOS Policy confirming that the NovoTTF-100A system falls within the DME benefit category. (Exh. 2, p. 75)

A Letter of Medical Necessity dated May 24, 2018, was written by Dr. MD, PHD requesting coverage for Optune treatment. (Exh. 2, pp. 7-9) The letter emphasized that the Appellant has exhausted all FDA-approved treatment that could benefit her in her current clinical scenario. (*Id.*) An assessment of need was completed on August 11, 2017. (Exh. 2 p. 10)

National Comprehensive Cancer Network (NCCN) guidelines contained in the record indicate that alternating electric field therapy is a recommended course of treatment. (*See attached CD*; Exh. 5) Alternating electric field therapy (Optune) + adjuvant temozolomide is a NCCN category 2A(category 1) recommendation following postoperative standard brain radiation therapy with concurrent temozolomide. (*Id.*)

The article from the Journal of the American Medical Association (JAMA) titled Maintenance Therapy with Tumor-Treating Fields Plus Temozolomide vs. Temozolomide Alone for Glioblastoma — A Randomized Clinical Trial describes the superior results in progression free survival as well as overall survival of glioblastoma patients using TTFields. (*See CD attached Exh 5*)

The Society of NeuroOncology organization conducted an internal, multicenter, prospective, randomized phase III trial in newly diagnosed GBM patients. (Exh. 2, p. 74) In the trial, after completion of radiotherapy with concomitant temozolomide (TMZ), patients were randomized (2:1) to adjuvant TMZ with NovoTTF or to adjuvant TMZ alone. (*Id.*) The study concluded that adjuvant TMZ chemotherapy and NovoTTF provided a clinically and statistically significant improvement in progression-free and overall survival, and should become the new standard of care against GBM. (*Id.*)

The Optune (NovoTTF-100A System) manual explained that Optune, for treatment of newly diagnosed and/or recurrent GBM, is a portable battery or power supply operated device which produces alternating electrical fields, called tumor treatment fields ("TTFields"), within the human body. (Exh. 2, pp. 49-73) Clinical data contained within the Optune (NovoTTF-100A System) manual concludes that the results of a pivotal trial in newly diagnosed GBM showed that Optune/TMZ extends progression free and overall survival significantly compared to patients receiving TMZ alone. (Exh. 2, p. 64)

Optune received pre-market approval by the Food and Drug Administration (FDA) for recurrent glioblastoma in April of 2011 following positive results of a controlled trial. (Exh. 2, pp. 76-80, 81-) A phase III trial of Optune (NovoTTF-100A System) from Novocure was halted due to statistically significant efficacy for the device in combination with chemotherapy to treatment newly diagnosed glioblastoma patients. (*See attached CD*; Exh. 5) Specifically, the trial was halted in order to offer the treatment to the remaining chemo-only group. (*Id.*) In 2015, Optune received pre-market approval by the FDA for newly diagnosed glioblastoma in combination with temozolomide after standard surgical resection and radiation therapy. (*See attached CD*; Exh. 5)

The record reflects that major insurance carriers such as Aetna, BCBS, Cigna, HealthPartners, Humana, United Healthcare, etc. have allowed for coverage for TTFT. (*See attached CD*; Exh. 5) The record also contains numerous in-depth peer-reviewed studies and articles showing the effectiveness of the device. (*Id.*)

The record also contains a letter directed to Mr. Justin M. Kelly, RN BSN from Novocure regarding a reconsideration request for TTFT LCD coverage criteria. (Exh. 5) The letter indicates that currently the TTFT LCD includes language indicating that coverage for recurrent glioblastoma multiforme (GBM) is not reasonable and necessary; however coverage of newly diagnosed GBM is not addressed. (*Id.*) A final decision following the valid reconsideration request submitted was expected to be issued on September 18, 2018. (*Id.*)

At the hearing, counsel provided argument in support of Medicare coverage for the Optune device at issue. (*Hearing CD*) Ms. Parrish indicated that the EOB was submitted and argued that quantification of effectiveness of a treatment is not a requirement for Medicare coverage. (*Id.*) Ms. Parrish noted that the Appellant's extended survival more demonstrates the effectiveness of her treatment. (*Id.*) Ms. Miles provided an overview regarding the Appellant's clinical history, course of treatment and current status. (*Id.*) Ms. Miles concluded that the Optune device was medically reasonable and necessary for the Appellant. (*Id.*)

Legal Framework

I. ALJ Review Authority **A. Jurisdiction**

An individual who, or an organization that is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services, provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. 42 C.F.R. § 405.1014; Social Security Act ("the Act") section 1869(b)(1)(A)). In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJ's within OMHA issue binding decisions of the Secretary, unless those decisions are later reviewed by the Medicare Appeals Council. (*Id.*)

For hearing requests filed on or after January 1, 2018, a party does not have a right to an ALJ hearing unless the remaining amount in controversy is \$160 after reduction for any Medicare payment already made and any applicable deductible and coinsurance amounts (42 CFR

§405.1006(b) and (d)(1)(i)-(ii); *Federal Register*, Vol. 82, No. 188, Pg. 45592-45593, Sept. 29, 2017, effective January 1, 2018).

To be considered timely, the request for hearing must be received by OMHA within sixty days after the Appellant receives the reconsideration decision. 42 C.F.R. § 405.1002(a)(1). The Appellant is presumed to have received the QIC's reconsideration five days after the date noted on the first page of the reconsideration, unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3).

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the Appellant's favor. 42 C.F.R. § 405.1032(a) However, if evidence presented before or during the hearing causes the ALJ to question a fully favorable decision he or she will notify the Appellant and will consider it an issue at the hearing. 42 C.F.R. § 405.1032(b) The ALJ may decide a case on the record and not conduct an oral hearing if the Appellant and all the parties indicate in writing that they do not wish to appear before the ALJ at an oral hearing or if an examination of the record supports a finding in favor of the Appellant on every issue. 42 C.F.R. § 405.1038

Unless the ALJ dismisses the hearing, the ALJ will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. 42 C.F.R. § 405.1046(a) The decision must be based on evidence offered at the hearing or otherwise admitted into the record. (*Id.*) An Appellant may offer new evidence for the first time at the ALJ level of appeal only upon a showing of good cause why the evidence was not submitted to the QIC or a prior decision maker. 42 C.F.R. § 405.1018 The ALJ will determine whether good cause exists for the late submission of the new evidence and may only consider the evidence in making a decision if good cause is found. *See* 42 C.F.R. §§ 405.1018, 405.1028 and 405.1030. This late evidence restriction does not apply to unrepresented beneficiaries or to oral testimony given at a hearing. *See* 42 C.F.R. § 405.1018(d).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue and issues a decision based on the hearing record. 42 C.F.R. § 405.1000(d) and Section 557 of the Administrative Procedure Act. *De novo* review requires the ALJ to review and evaluate the evidence without regard to the findings of prior determinations on the claim and make an independent assessment relying upon the evidence and controlling laws. All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Act and applicable implementing regulations, are binding on ALJs. 42 C.F.R. § 405.1063.

The burden of proving each element of a Medicare claim lies with the Appellant by preponderance of the evidence. *See* Act §§ 1814(a)(1), 1815(b), and 1833(e); 42 C.F.R. § 424.5(a)(6), 405.1018, 405.1028, and 405.1030.

II. Principles of Law

A. Statutes and Regulations

Section 1831 of the Act establishes a supplementary insurance program for the aged and disabled. This insurance program, commonly referred to as Part B of Medicare, is financed through premium payments by enrollees together with contributions from funds appropriated by the Federal Government. §1831; 42 U.S.C. 1395j. The program allows for the reimbursement of physicians' services including surgery, consultation, and office visits. §1861(q); 42 U.S.C. 1395x(q)

The standard for payment of these services is found in section 1862(a)(1)(A) of the Act. There, the Act states that no payment may be made "...for items and services...[which] are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Section 1833(e) of the Act provides that payment will not be made unless sufficient information is furnished to determine the amounts due to the provider. *See also* 42 CFR §424.5(6).

Section 1862(a)(1)(A) of the Act provides that "[n]otwithstanding any other provision of the Act, no payment shall be made for any expenses incurred for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." *See also* 42 C.F.R. §411.15(k).

Section 1866(a)(1)(A)(i) of the Act provides that "[a]ny provider of services (except a fund designated for purposes of section 1814(g) and section 1835(e)) shall be qualified to participate under this title and shall be eligible for payments under this title if it files with the Secretary an agreement not to charge, except as provided in paragraph (2), any individual or any other person for items or services for which such individual is entitled to have payment made under this title (or for which he would be so entitled if such provider of services had complied with the procedural and other requirements under or pursuant to this title or for which such provider is paid pursuant to the provisions of section 1814(e)) of the Act." *See also* 42 C.F.R. §489.1 *et seq.* (setting forth the terms and limitations on provider agreements).

Section 1879 of the Act limits the liability of the Beneficiary and providers of services if the services are found to be not medically reasonable and necessary under Section 1862(a)(1)(A) or care was custodial in nature under Section 1862(a)(9) of the Act. Payment will only be made pursuant to this section if neither the Beneficiary nor the provider knew or could reasonably have been expected to know that the services were not covered. *See also* 42 C.F.R. §411.404; 42 C.F.R. §411.406.

B. Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than a National Coverage Determination (NCD), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local medical review policies (LMRPs) or local coverage determinations (LCDs).

Section 1869(f)(1) of the Act provides that NCDs are binding upon Administrative Law Judges. *See also* 42 CFR §405.1060. *Medicare National Coverage Determinations Manual, Pub. 100-03, Ch. 1, sec. 280* ("NCD 280.1") provides a mandatory statement as to what constitutes equipment that meets the definition of DME, as follows:

"The term DME is defined as equipment which:

- * Can withstand repeated use; i.e., could normally be rented and used by successive patients;
- * Is primarily and customarily used to serve a medical purpose;
- * Generally is not useful to a person in the absence of illness or injury; and,
- * Is appropriate for use in a patient's home."

Section §1869(f)(2) of the Act provides that Administrative Law Judges will give substantial deference to LCDs, LMRPs, or CMS program guidance when applicable, and if they do not follow the policy they must explain why in their decision. *See also* 42 CFR §405.1062. The Local Coverage Determination Policy applicable to this case. The LCD at issue is L34823 and Policy Article 52711. LCD L34823 provides as follows:

Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

GENERAL

A Detailed Written Order (DWO) (if applicable) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed DWO, the claim shall be denied as not reasonable and necessary.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor

Policy Article 52711 provides in pertinent part as follows:

Code E0766 describes devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers.

This code is inclusive of all associated supplies necessary for the effective use of code E0766 including, but not limited to, transducers/surface electrodes, lead wires, adhesive patches, connectors, conductive gel and skin preps.

Medicare Benefit Policy Manual, Pub. 100-02 ("CMS Pub. 100-02"), Ch. 15, §110.1, also provides guidance pertaining to Medicare coverage of DME, and explains that

Expenses incurred by a beneficiary for the rental or purchases of durable medical equipment (DME) are reimbursable if the following three requirements are met:

- The equipment meets the definition of DME (§110.1);
- The equipment is necessary and reasonable for the treatment of the patient's illness or injury or to improve the functioning of his or her malformed body member (§110.1); and
- The equipment is used in the patient's home.

Ch. 15, §110.1(A) further explains as follows:

- Equipment which is primarily and customarily used for a nonmedical purpose may not be considered "medical" equipment for which payment can be made under the medical insurance program. This is true even though the item has some remote medically related use. For example, in the case of a cardiac patient, an air conditioner might possibly be used to

lower room temperature to reduce fluid loss in the patient and to restore an environment conducive to maintenance of the proper fluid balance. Nevertheless, because the primary and customary use of an air conditioner is a nonmedical one, the air conditioner cannot be deemed to be medical equipment for which payment can be made.

- Other devices and equipment used for environmental control or to enhance the environmental setting in which the beneficiary is placed are not considered covered DME. These include, for example, room heaters, humidifiers, dehumidifiers, and electric air cleaners. Equipment which basically serves comfort or convenience functions or is primarily for the convenience of a person caring for the patient, such as elevators, stairway elevators, and posture chairs, do not constitute medical equipment. Similarly, physical fitness equipment (such as an exercycle), first-aid or precautionary-type equipment (such as preset portable oxygen units), self-help devices (such as safety grab bars), and training equipment (such as Braille training texts) are considered nonmedical in nature.

Medicare Program Integrity Manual, Pub. 100-08, ("CMS Pub. 100-08"), Ch. 5, provides guidance as to documentation for DME claims, including the requirement of both physician orders for DME and supporting documentation for medical necessity and delivery. Ch. 5, also provides guidance as to patient documentation requirements to support that Medicare coverage criteria for items of DME have been met.

For any DMEPOS [Durable Medical Equipment Prosthetics Orthotics and Supplies] item to be covered by Medicare, the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the patient's diagnosis and other pertinent information including, but not limited to, duration of the patient's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc. . . . neither a physician's order nor a CMN [certificate of medical necessity] . . . nor a supplier prepared statement nor a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier. There must be information in the patient's medical record that supports the medical necessity for the item and substantiates the answers on the CMN (if applicable) . . . or information on a supplier prepared statement or physician attestation (if applicable). . . . The patient's medical record is not limited to the physician's office records. It may include hospital, nursing home, or HHA records and records from other health care professionals. *CMS Pub. 100-08, Ch. 5, §5.7.*

Medicare Program Integrity Manual, Pub. 100-08 ("CMS Pub. 100-08"), Ch. 13, §13.5.1 explains the reasonable and necessary provisions in LCDs as follows:

Contractors shall describe in the draft LCD the circumstances under which the item or service is reasonable and necessary under 1862(a)(1)(A). Contractors shall

consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
 - Furnished in a setting appropriate to the patient's medical needs and condition;
 - Ordered and furnished by qualified personnel;
 - One that meets, but does not exceed, the patient's medical need; and
 - At least as beneficial as an existing and available medically appropriate alternative.

Analysis

The QIC denied coverage on the basis that there was insufficient documentation to quantify the effects of the device for this beneficiary and no additional medical records have been submitted to explain why this particular beneficiary should be considered for this treatment. (Exh. 1, pp. 1-9) Additionally, the QIC added that no documentation had been received to show the suggested manufacturer retail price for the service(s) billed. (*Id.*) The QIC held Novocure liable for the denied charges. (*Id.*)

At the hearing, Ms. Parrish argued that quantification of effectiveness of a treatment is not a requirement for Medicare coverage. Ms. Parrish further argued that that the EOB was submitted. The undersigned agrees.

Local Coverage Determination L34823, promulgated by Medicare Contractors CGS Administrators, LLC and Noridian Healthcare Solutions, LLC, which became effective January 1, 2017 and as currently in effect, states that "Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary⁴." Pursuant to 42 C.F.R. § 405.1062(a) an ALJ is not bound by contractor LCDs or CMS program guidance, such as program memoranda and manual instructions, "but will give substantial deference to these policies if they are applicable to a particular case." An ALJ must explain the reason for not following such a policy in a specific case. 42 C.F.R. § 405.1062(b). Any decision to disregard a policy "applies only to the specific claim being considered and does not have precedential effect." (*Id.*)

In the instant appeal, the Appellant, G. Scotch, a then 70 year old male female was diagnosed with a left precentral gyrus glioblastoma⁵(GBM) (WHO grade IV) in May 2017. Prior to her

⁴ The undersigned notes that LCD L34823 does not articulate the reason the Contractor has determined categorically that the device is not reasonable and necessary.

⁵ **Glioblastoma (GBM)** is an aggressive type of cancer that can occur in the brain or spinal cord. GBM tumors form from cells called astrocytes that support nerve cells. GBM can occur at any age but tends to occur more often in

diagnosis, the Appellant was experiencing expressive aphasia and slurred speech. Upon presentation to the hospital, an MRI revealed an enhancing necrotic mass at the left post central gyrus. On May 30, 2017 the Appellant underwent a left frontal craniotomy with subtotal resection with pathology showing glioblastoma. Following surgery, her clinician prescribed chemoradiation therapy and the Optune System. The record reflects the Appellant signed the Optune Service Agreement, delivery confirmation and patient information and consent forms on August 23, 2017. The record reflects the Appellant underwent the prescribed treatment. Novocure issued invoices for the NOVO-TTF 100A dated August 23, 2017, September 23, 2017, October 23, 2017 and November 23, 2017 in the amount of \$21,000 for each month.

After a careful and thorough review of Appellant's arguments and the evidence in the record, the undersigned has declined to follow the applicable LCD in light of FDA approval, acceptance by major insurance carriers, peer-reviewed medical literature, general acceptance by the medical community and the specific evidence of medical necessity in this case. Specifically, in this regard the Appellant submitted documentation confirming the pre-market approval by the FDA for recurrent glioblastoma in April of 2011 following positive results of a controlled trial and later pre-market approval in October 2015 for newly diagnosed glioblastoma in combination with temozolomide after standard surgical resection and radiation therapy.

The Appellant also submitted an article from the Journal of the American Medical Association (JAMA) titled Maintenance Therapy with Tumor-Treating Fields Plus Temozolomide Vs. Temozolomide Alone for Glioblastoma — A Randomized Clinical Trial and the National Comprehensive Cancer Network (NCCN) guidelines. The article describes the superior results in progression free survival as well as overall survival of glioblastoma patients using TTFields; while the National Comprehensive Cancer Network (NCCN) guidelines issued a level 1 recommendation that TTFT should be used to treatment glioblastoma. Additionally, the record contains numerous payer policies for TTFT from major insurance carriers, including but not limited to, Aetna, BCBS, Cigna, HealthPartners, Humana, United Healthcare and in-depth peer-reviewed studies showing the effectiveness of the device.

Furthermore, the medical records reflect that the use of the Optune device has made a meaningful contribution to the treatment of the Appellant's glioblastoma. Specifically, the Appellant's most recent MRI dated March 27, 2018 showed stable findings compared to previous scans and progress notes confirm the Appellant remains clinically and radiographically stable.

Based on the foregoing, the undersigned finds that the E0766 (electrical stimulation device used for cancer treatment) furnished to the Appellant on August 23, 2017, September 23, 2017, October 23, 2017 and November 23, 2017 by Novocure (Provider/Supplier) was medically reasonable and necessary and is covered by Medicare.

Conclusions of Law

Medicare coverage exists for the E0766 (electrical stimulation device used for cancer treatment)

older adults, and can cause worsening headaches, nausea, vomiting and seizures. GBM, also known as glioblastoma multiforme, can be very difficult to treat and a cure is often not possible. Treatments may slow progression of the cancer and reduce signs and symptoms (See Mayo Clinic at <https://www.mayoclinic.org/diseases-conditions/glioblastoma/cdc-20350148>).


provided to the Beneficiary on August 23, 2017, September 23, 2017, October 23, 2017 and November 23, 2017.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED

Dated: DEC 19 2018



Scott Tews
U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Miami, Florida

Appeal of:

OMHA Appeal No.: 1-7718819982

Beneficiary:

Medicare: Part B

Medicare No.:

Before: Scott Tews
U.S. Administrative Law Judge

DECISION

After carefully considering the arguments and evidence presented in the record, a **FULLY FAVORABLE** decision is entered in the appeal of (Appellant/Beneficiary).

Procedural History

A claim was submitted seeking Medicare coverage and payment for an E0766 (electrical stimulation device used for cancer treatment) furnished to the Appellant on July 27, 2017, August 27, 2017 and September 27, 2017 (dates of service) by Novocure (Provider/Supplier). Medicare coverage was denied at the initial determination and redetermination levels by CGS, DME MAC Jurisdiction C, the Medicare Administrative Contractor (Contractor). (Exh. 1) The Appellant requested reconsideration and on June 20, 2018, C2C Innovative Solutions, Inc., the Medicare Qualified Independent Contractor (QIC) upheld the prior denials. (*Id.*) The QIC denied coverage on the basis that the medical documentation did not support the need for the device and there was insufficient documentation to quantify the effects of the device. (*Id.*) Further, the QIC held Novocure liable for the denied charges. (*Id.*)

The Appellant requested an Administrative Law Judge (ALJ) hearing, which was received by the Office of Medicare Hearings and Appeals (OMHA) on July 26, 2018. (Exh. 3) Along with the request for an ALJ hearing, an Appointment of Representative form was submitted designating Debra M. Parrish, Esq. as counsel for the Appellant. (*Id.*) The hearing request was timely filed and the amount in controversy satisfies the jurisdictional requirement for an ALJ hearing pursuant to Title XVIII of the Social Security Act (Act) § 1869(b)(1)(E). (Exh. 1; Exh. 3)

Within the Request for Hearing, Attorney Parrish requested pending dates of service be aggregated to this appeal. (Exh. 3) Dates included September 27, 2016, October 27, 2016, November 27, 2016, December 27, 2016; January 27, 2017, February 27, 2017, March 27, 2017; April 27, 2017, May 27, 2017 and June 27, 2017. Upon review, the undersigned has determined that these requested dates cannot be added to the dates of service in this current appeal.

On October 4, 2018, the undersigned ALJ held a telephonic hearing from the OMHA Miami Field Office. The QIC was provided with a notice of hearing, but did not attend. Attendees at the hearing included: Debra Parrish, Counsel for the Appellant, Julie Miles, Tim Parks and Dan McCoy. The Appellant's representative submitted a pre-hearing brief with additional evidence to the undersigned. The additional evidence has been admitted into the record as Exhibit 5¹. The record includes Exhibits one (1) through five (5), which were admitted without objection and the recorded hearing testimony.

Issues

Whether Medicare coverage exists for the E0766 (electrical stimulation device used for cancer treatment) provided to the Appellant on July 27, 2017, August 27, 2017 and September 27, 2017, and, if not, who is responsible for the non-covered charges?

Findings of Fact

The Appellant, a then 55 year old male was diagnosed with Glioblastoma multiforme² in April 2014. (Exh. 2, p. 26) Prior to his diagnosis, the Appellant experienced terrible headaches and had difficulty processing things. (Exh. 1, p. 22) On April 14, 2014, the Appellant underwent a left parietal craniotomy and resection of brain tumor performed by Dr. Tandon. (Exh. 2, p. 29) On September 10, 2014, the Appellant underwent a reopening of the left parietal craniotomy and resection of recurrent tumor as well as radiation necrosis. (*Id.*) On September 29, 2016 the Appellant underwent an MRI that reflected stable postoperative changes of the left parieto-occipital craniectomy with underlying resection cavity within the left parietal lobe, stable enhancement along the inferior and medial margins of the resection cavity and unchanged adjacent FLAIR hyperintensity. (Exh. 2, p. 29) Final report dated February 1, 2017 notes the Appellant completed 30 Temodar³ cycles and 22 infusions of Avastin/Irinotecan and was still on the Optune device with Temodar. (Exh. 2, pp. 26-28) The record reflects the Appellant tolerated the TTF device very well. (Exh. 2, p. 26)

At the lower levels, the Appellant submitted a letter to Contractor dated February 16, 2017 indicating that TTF was the Appellant's best option to treat his fatal disease⁴. (Exh. 1, pp. 21-22, 34-35) The Appellant noted that he began using Optune on May 27, 2016 and it has kept his tumor at bay. (*Id.*) The Appellant further noted that the Optune device is covered by numerous local and national insurance carriers. (*Id.*)

¹ The evidence submitted by the Appellant's representative has been admitted into the record pursuant to 42 C.F.R. § 405.1018(d)(2).

² **Glioblastoma (GBM)** is an aggressive type of cancer that can occur in the brain or spinal cord. GBM tumors form from cells called astrocytes that support nerve cells. GBM can occur at any age but tends to occur more often in older adults, and can cause worsening headaches, nausea, vomiting and seizures. GBM, also known as glioblastoma multiforme, can be very difficult to treat and a cure is often not possible. Treatments may slow progression of the cancer and reduce signs and symptoms (See Mayo Clinic at <https://www.mayoclinic.org/diseases-conditions/glioblastoma/cdc-20350148>).

³ **Temozolomide** (brand name: **Temodar**) is a chemotherapy drug used to treat GBM (See Chemocare at <http://chemocare.com/chemotherapy/drug-info/Temozolomide.aspx>).

⁴ The article titled *NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma: A randomized phase III trial of a novel treatment and modality* contained in the record explains that glioblastoma is the most prevalent primary malignant brain tumor in adults and the median survival with optimal therapy is only 15 months from diagnosis, and most tumors recur within 9 months of initial treatment. (Exh. 2, pp. 121-131)

The record contains an Optune Prescription Form prescribing 6 months of Optune for the Appellant due to malignant neoplasm of brain (C71.9), Glioblastoma WHO-World Health Organization Grade 4. (Exh. 2, pp. 4-5) Novocure issued invoices for the NOVO-TTF 100A in the amount of \$21,000 for each month dated July 27, 2017, August 27, 2017 and September 27, 2017. (Exh. 2, pp. 1-3) The Optune Service Agreement and delivery confirmation was signed by the Appellant on May 27, 2016. (Exh. 2, pp. 10-21)

The record also contains a Letter of Medical Necessity dated April 25, 2017, written by Dr.

MD, PHD requesting coverage for Optune treatment. (Exh. 2, pp. 6-7) The letter emphasized that the Appellant has exhausted all FDA-approved treatment that could benefit him in his current clinical scenario. (*Id.*) An assessment of need was completed on May 25, 2016. (Exh. 2 p. 9)

National Comprehensive Cancer Network (NCCN) guidelines version 1.2016 provided treatment options for glioblastoma to include chemotherapy or re-irradiation (category 2B) or alternating electric field therapy. (Exh. 2, pp. 30-33)

The article from the Journal of the American Medical Association (JAMA) titled Maintenance Therapy with Tumor-Treating Fields Plus Temozolomide vs. Temozolomide Alone for Glioblastoma — A Randomized Clinical Trial describes the superior results in progression free survival as well as overall survival of glioblastoma patients using TTFields. (Exh 5. *Attached CD*)

The article titled NovoTTF-100A: a new treatment modality for recurrent glioblastoma concludes that NovoTTF-100A has comparable efficacy, and less toxicity, when compared to conventional drug treatments in the recurrence setting. (Exh. 2, p. 135)

Optune received pre-market approval by the Food and Drug Administration (FDA) for recurrent glioblastoma in April of 2011 following positive results of a controlled trial. (Exh. 2, pp. 71-120) A phase III trial of Optune (NovoTTF-100A System) from Novocure was halted due to statistically significant efficacy for the device in combination with chemotherapy to treatment newly diagnosed glioblastoma patients. (*See attached CD*; Exh. 5) Specifically, the trial was halted in order to offer the treatment to the remaining chemo-only group. (*Id.*) In 2015, Optune received pre-market approval by the FDA for newly diagnosed glioblastoma in combination with temozolomide after standard surgical resection and radiation therapy. (*See attached CD*; Exh. 5)

The record reflects that major insurance carriers such as Aetna, BCBS, Cigna, HealthPartners, Humana, United Healthcare, etc. have allowed for coverage for TTFT. (*See attached CD*; Exh. 5) The record also contains numerous in-depth peer-reviewed studies and articles showing the effectiveness of the device. (*Id.*)

At the hearing, Ms. Parrish emphasized that it has been four years since the Appellant was diagnosed with glioblastoma and he is still alive, stable and the disease is well managed. (*Hearing CD*) Ms. Parrish argued that the applicable LCD on its face does not reflect consideration of the peer reviewed literature, the consensus of experts or that this device is included in the NCCN guidelines. (*Id.*) Counsel also added that the applicable LCD is currently under review right now. (*Id.*)

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services, provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. 42 C.F.R. § 405.1014; Social Security Act (“the Act”) section 1869(b)(1)(A)). In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJ’s within OMHA issue binding decisions of the Secretary, unless those decisions are later reviewed by the Medicare Appeals Council. (*Id.*)

For hearing requests filed on or after January 1, 2018, a party does not have a right to an ALJ hearing unless the remaining amount in controversy is \$160 after reduction for any Medicare payment already made and any applicable deductible and coinsurance amounts (42 CFR §405.1006(b) and (d)(1)(i)-(ii); *Federal Register*, Vol. 82, No. 188, Pg. 45592-45593, Sept. 29, 2017, *effective January 1, 2018*).

To be considered timely, the request for hearing must be received by OMHA within sixty days after the Appellant receives the reconsideration decision. 42 C.F.R. § 405.1002(a)(1). The Appellant is presumed to have received the QIC’s reconsideration five days after the date noted on the first page of the reconsideration, unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3).

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the Appellant’s favor. 42 C.F.R. § 405.1032(a) However, if evidence presented before or during the hearing causes the ALJ to question a fully favorable decision he or she will notify the Appellant and will consider it an issue at the hearing. 42 C.F.R. § 405.1032(b) The ALJ may decide a case on the record and not conduct an oral hearing if the Appellant and all the parties indicate in writing that they do not wish to appear before the ALJ at an oral hearing or if an examination of the record supports a finding in favor of the Appellant on every issue. 42 C.F.R. § 405.1038

Unless the ALJ dismisses the hearing, the ALJ will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. 42 C.F.R. § 405.1046(a) The decision must be based on evidence offered at the hearing or otherwise admitted into the record. (*Id.*) An Appellant may offer new evidence for the first time at the ALJ level of appeal only upon a showing of good cause why the evidence was not submitted to the QIC or a prior decision maker. 42 C.F.R. § 405.1018 The ALJ will determine whether good cause exists for the late submission of the new evidence and may only consider the evidence in making a decision if good cause is found. *See* 42 C.F.R. §§ 405.1018, 405.1028 and 405.1030. This late evidence restriction does not apply to unrepresented beneficiaries or to oral testimony given at a hearing. *See* 42 C.F.R. § 405.1018(d).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue and issues a decision based on the hearing record. 42 C.F.R. § 405.1000(d) and Section 557 of the Administrative Procedure Act. *De novo* review requires the ALJ to review and evaluate the evidence without regard to the findings of prior determinations on the claim and make an independent assessment relying upon the evidence and controlling laws. All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Act and applicable implementing regulations, are binding on ALJs. 42 C.F.R. § 405.1063.

The burden of proving each element of a Medicare claim lies with the Appellant by preponderance of the evidence. *See* Act §§ 1814(a)(1), 1815(b), and 1833(e); 42 C.F.R. § 424.5(a)(6), 405.1018, 405.1028, and 405.1030.

II. Principles of Law

A. Statutes and Regulations

Section 1831 of the Act establishes a supplementary insurance program for the aged and disabled. This insurance program, commonly referred to as Part B of Medicare, is financed through premium payments by enrollees together with contributions from funds appropriated by the Federal Government. §1831; 42 U.S.C. 1395j. The program allows for the reimbursement of physicians' services including surgery, consultation, and office visits. §1861(q); 42 U.S.C. 1395x(q)

The standard for payment of these services is found in section 1862(a)(1)(A) of the Act. There, the Act states that no payment may be made "...for items and services...[which] are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Section 1833(e) of the Act provides that payment will not be made unless sufficient information is furnished to determine the amounts due to the provider. *See also* 42 CFR §424.5(6).

Section 1862(a)(1)(A) of the Act provides that "[n]otwithstanding any other provision of the Act, no payment shall be made for any expenses incurred for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." *See also* 42 C.F.R. §411.15(k).

Section 1866(a)(1)(A)(i) of the Act provides that "[a]ny provider of services (except a fund designated for purposes of section 1814(g) and section 1835(e)) shall be qualified to participate under this title and shall be eligible for payments under this title if it files with the Secretary an agreement not to charge, except as provided in paragraph (2), any individual or any other person for items or services for which such individual is entitled to have payment made under this title (or for which he would be so entitled if such provider of services had complied with the procedural and other requirements under or pursuant to this title or for which such provider is paid pursuant to the provisions of section 1814(e)) of the Act." *See also* 42 C.F.R. §489.1 *et seq.* (setting forth the terms and limitations on provider agreements).

Section 1879 of the Act limits the liability of the Beneficiary and providers of services if the services are found to be not medically reasonable and necessary under Section 1862(a)(1)(A) or care was custodial in nature under Section 1862(a)(9) of the Act. Payment will only be made pursuant to this section if neither the Beneficiary nor the provider knew or could reasonably have been expected to know that the services were not covered. *See also* 42 C.F.R. §411.404; 42 C.F.R. §411.406.

B. Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than a National Coverage Determination (NCD), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local medical review policies (LMRPs) or local coverage determinations (LCDs).

Section 1869(f)(1) of the Act provides that NCDs are binding upon Administrative Law Judges. *See also* 42 CFR §405.1060. *Medicare National Coverage Determinations Manual, Pub. 100-03, Ch. 1, sec. 280* ("NCD 280.1") provides a mandatory statement as to what constitutes equipment that meets the definition of DME, as follows:

"The term DME is defined as equipment which:

- * Can withstand repeated use; i.e., could normally be rented and used by successive patients;
- * Is primarily and customarily used to serve a medical purpose;
- * Generally is not useful to a person in the absence of illness or injury; and,
- * Is appropriate for use in a patient's home."

Section §1869(f)(2) of the Act provides that Administrative Law Judges will give substantial deference to LCDs, LMRPs, or CMS program guidance when applicable, and if they do not follow the policy they must explain why in their decision. *See also* 42 CFR §405.1062. The Local Coverage Determination Policy applicable to this case. The LCD at issue is L34823 and Policy Article 52711. LCD L34823 provides as follows:

Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the "reasonable and necessary" criteria contained in this LCD there are

other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

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- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the “reasonable and necessary” criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

GENERAL

A Detailed Written Order (DWO) (if applicable) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed DWO, the claim shall be denied as not reasonable and necessary.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor

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Code E0766 describes devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers.

This code is inclusive of all associated supplies necessary for the effective use of code E0766 including, but not limited to, transducers/surface electrodes, lead wires, adhesive patches, connectors, conductive gel and skin preps.

Medicare Benefit Policy Manual, Pub. 100-02 (“CMS Pub. 100-02”), Ch. 15, §110.1, also provides guidance pertaining to Medicare coverage of DME, and explains that

Expenses incurred by a beneficiary for the rental or purchases of durable medical equipment (DME) are reimbursable if the following three requirements are met:

- The equipment meets the definition of DME (§110.1);
- The equipment is necessary and reasonable for the treatment of the patient's illness or injury or to improve the functioning of his or her malformed body member (§110.1); and
- The equipment is used in the patient's home.

Ch. 15, §110.1(A) further explains as follows:

- Equipment which is primarily and customarily used for a nonmedical purpose may not be considered "medical" equipment for which payment can be made under the medical insurance program. This is true even though the item has some remote medically related use. For example, in the case of a cardiac patient, an air conditioner might possibly be used to lower room temperature to reduce fluid loss in the patient and to restore an environment conducive to maintenance of the proper fluid balance. Nevertheless, because the primary and customary use of an air conditioner is a nonmedical one, the air conditioner cannot be deemed to be medical equipment for which payment can be made.
- Other devices and equipment used for environmental control or to enhance the environmental setting in which the beneficiary is placed are not considered covered DME. These include, for example, room heaters, humidifiers, dehumidifiers, and electric air cleaners. Equipment which basically serves comfort or convenience functions or is primarily for the convenience of a person caring for the patient, such as elevators, stairway elevators, and posture chairs, do not constitute medical equipment. Similarly, physical fitness equipment (such as an exercycle), first-aid or precautionary-type equipment (such as preset portable oxygen units), self-help devices (such as safety grab bars), and training equipment (such as Braille training texts) are considered nonmedical in nature.

Medicare Program Integrity Manual, Pub. 100-08, ("CMS Pub. 100-08"), Ch. 5, provides guidance as to documentation for DME claims, including the requirement of both physician orders for DME and supporting documentation for medical necessity and delivery. *Ch. 5*, also provides guidance as to patient documentation requirements to support that Medicare coverage criteria for items of DME have been met.

For any DMEPOS [Durable Medical Equipment Prosthetics Orthotics and Supplies] item to be covered by Medicare, the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the patient's diagnosis and other pertinent information including, but not limited to, duration of the patient's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past

experience with related items, etc. . . . neither a physician's order nor a CMN [certificate of medical necessity] . . . nor a supplier prepared statement nor a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier. There must be information in the patient's medical record that supports the medical necessity for the item and substantiates the answers on the CMN (if applicable) . . . or information on a supplier prepared statement or physician attestation (if applicable). . . . The patient's medical record is not limited to the physician's office records. It may include hospital, nursing home, or HHA records and records from other health care professionals. *CMS Pub. 100-08, Ch. 5, §5.7.*

Medicare Program Integrity Manual, Pub. 100-08 ("CMS Pub. 100-08"), Ch. 13, §13.5.1 explains the reasonable and necessary provisions in LCDs as follows:

Contractors shall describe in the draft LCD the circumstances under which the item or service is reasonable and necessary under 1862(a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
 - Furnished in a setting appropriate to the patient's medical needs and condition;
 - Ordered and furnished by qualified personnel;
 - One that meets, but does not exceed, the patient's medical need; and
 - At least as beneficial as an existing and available medically appropriate alternative.

Analysis

The QIC denied coverage on the basis that the medical documentation did not support the need for the device and there was insufficient documentation to quantify the effects of the device. (Exh. 1, pp. 1-7) Further, the QIC held Novocure liable for the denied charges. (*Id.*) Ms. Parrish argued that the applicable LCD on its face does not reflect consideration of the peer reviewed literature, the consensus of experts or that this device is included in the NCCN guidelines. (*Id.*) The undersigned agrees with the Appellant.

Local Coverage Determination L34823, promulgated by Medicare Contractors CGS Administrators, LLC and Noridian Healthcare Solutions, LLC, which became effective January 1, 2017 and as currently in effect, states that "Tumor treatment field therapy (E0766) will be

denied as not reasonable and necessary⁵.” Pursuant to 42 C.F.R. § 405.1062(a) an ALJ is not bound by contractor LCDs or CMS program guidance, such as program memoranda and manual instructions, “but will give substantial deference to these policies if they are applicable to a particular case.” An ALJ must explain the reason for not following such a policy in a specific case. 42 C.F.R. § 405.1062(b). Any decision to disregard a policy “applies only to the specific claim being considered and does not have precedential effect.” (*Id.*)

In the instant appeal, the Appellant, a then 55 year old male was diagnosed with Glioblastoma multiforme in April 2014. Prior to his diagnosis, the Appellant experienced terrible headaches and had difficulty processing things. On April 14, 2014, the Appellant underwent a left parietal craniotomy and resection of brain tumor performed by Dr. Tandon. On September 10, 2014, the Appellant underwent a reopening of the left parietal craniotomy and resection of recurrent tumor as well as radiation necrosis. On September 29, 2016 the Appellant underwent an MRI that reflected stable postoperative changes of the left parieto-occipital craniectomy with underlying resection cavity within the left parietal lobe, stable enhancement along the inferior and medial margins of the resection cavity and unchanged adjacent FLAIR hyperintensity. Final report dated February 1, 2017 notes the Appellant completed 30 Temodar cycles and 22 infusions of Avastin/Irinotecan and was still on the Optune device with Temodar. Currently, it has been four years since the Appellant was diagnosed with Glioblastoma and he is still alive and stable.

After a thorough review of the record, the undersigned has declined to follow the applicable LCD in light of FDA approval, acceptance by major insurance carriers, peer-reviewed medical literature, general acceptance by the medical community and the specific evidence of medical necessity in this case. Specifically, in this regard the Appellant submitted documentation confirming the pre-market approval by the FDA for recurrent glioblastoma in April of 2011 following positive results of a controlled trial and later pre-market approval in October 2015 for newly diagnosed glioblastoma in combination with temozolomide after standard surgical resection and radiation therapy.

The Appellant submitted an article from the Journal of the American Medical Association (JAMA) titled Maintenance Therapy with Tumor-Treating Fields Plus Temozolomide Vs. Temozolomide Alone for Glioblastoma — A Randomized Clinical Trial which describes the superior results in progression free survival as well as overall survival of glioblastoma patients using TTFields. Additionally, the Appellant submitted the National Comprehensive Cancer Network (NCCN) guidelines version 1.2016 which shows that treatment options for glioblastoma include chemotherapy or re-irradiation (category 2B) or alternating electric field therapy, as generally accepted by the medical community. Additionally, the record contains numerous payer policies for TTFT from major insurance carriers, including but not limited to, Aetna, BCBS, Cigna, HealthPartners, Humana, United Healthcare and in-depth peer-reviewed studies showing the effectiveness of the device. Moreover, the Appellant submitted a Letter of Medical Necessity for the device dated April 25, 2017, written by Dr. [REDACTED] MD, PHD indicating that the Appellant had exhausted all FDA-approved treatment that could benefit him. Last, the record shows it has been four years since the Appellant was diagnosed with Glioblastoma and he is still alive, stable and the disease is well managed.

⁵ The undersigned notes that LCD L34823 does not articulate the reason the Contractor has determined categorically that the device is not reasonable and necessary.

Based on the foregoing, the undersigned finds that the E0766 (electrical stimulation device used for cancer treatment) furnished to the Appellant on July 27, 2017, August 27, 2017 and September 27, 2017 by Novocure (Provider/Supplier) was medically reasonable and necessary and is covered by Medicare.

Conclusions of Law


Medicare coverage exists for the E0766 (electrical stimulation device used for cancer treatment) provided to the Appellant on July 27, 2017, August 27, 2017 and September 27, 2017.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED

Dated: DEC 19 2018



Scott Tews
U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Miami, Florida

Appeal of:

OMHA Appeal No.: **1-7915330299**

Beneficiary:

Medicare: **Part B**

Medicare No.:

Before: **Scott Tews**
U.S. Administrative Law Judge

DECISION

After carefully considering the arguments and evidence presented in the record, a **FULLY FAVORABLE** decision is entered in the appeal of (Appellant/Beneficiary).

Procedural History

A claim was submitted seeking Medicare coverage and payment for an E0766 (electrical stimulation device used for cancer treatment) furnished to the Appellant on September 21, 2017, October 21, 2017, November 21, 2017 and December 21, 2017 (dates of service) by Novocure (Provider/Supplier). Medicare coverage was denied at the initial determination and redetermination levels by CGS Administrators, the Medicare Administrative Contractor (Contractor). (Exh. 1) The Appellant requested reconsideration and on August 15, 2018, C2C Innovative Solutions, Inc., the Medicare Qualified Independent Contractor (QIC) upheld the prior denials. (*Id.*) The QIC denied coverage on the basis that there was insufficient documentation to quantify the effects of the device for this beneficiary. (*Id.*) The QIC also held that currently published studies in the medical literature do not clearly document the effectiveness of this device. (*Id.*) According, based on the available documentation, the requirements outline in the LCD, NCD, PIM, and IOM have not been met. (*Id.*) The QIC further held Novocure liable for the denied charges. (*Id.*)

The Appellant requested an Administrative Law Judge (ALJ) hearing, which was received by the Office of Medicare Hearings and Appeals (OMHA) on September 28, 2018. (Exh. 3) Along with the request for an ALJ hearing, an Appointment of Representative form was submitted designating Debra M. Parrish, Esq. as counsel for the Appellant. (*Id.*) The hearing request was timely filed and the amount in controversy satisfies the jurisdictional requirement for an ALJ hearing pursuant to Title XVIII of the Social Security Act (Act) § 1869(b)(1)(E). (Exh. 1; Exh. 3)

On November 26, 2018, the undersigned ALJ held a telephonic hearing from the OMHA Miami Field Office. The QIC was provided with a notice of hearing, but did not attend. Attendees at the

hearing included: Debra Parrish, Counsel for the Appellant and Julie Miles. The Appellant's representative submitted a pre-hearing brief with additional evidence to the undersigned. The additional evidence has been admitted into the record as Exhibit 5¹. The record includes Exhibits one (1) through five (5), which were admitted without objection and the recorded hearing testimony.

Issues

Whether Medicare coverage exists for the E0766 (electrical stimulation device used for cancer treatment) provided to the Appellant on September 21, 2017, October 21, 2017, November 21, 2017 and December 21, 2017, and, if not, who is responsible for the non-covered charges?

Findings of Fact

The Appellant, a then 70 year old male female presented to the hospital on July 24, 2016 with complaints of dropping things out of her left hand. (Exh. 2, pp. 34-36) Specifically, the Appellant first noticed the difficulty with hand strength approximately 2 weeks prior to her presentation and the symptoms persisted and progressed. (*Id.*) She ultimately felt more weakness in the left hand and came to the emergency department. (*Id.*) A CT scan of the head showed a right sided brain lesion 4 x 4.5 cm. (*Id.*) An brain MRI taken on July 25, 2016 showed a right posterior frontal lobe 4.8 x 4.5 x 5.0 cm cystic mass with a mild amount of vasogenic edema. (*Id.*) The Appellant then underwent a stealth guided stereofactic craniotomy with microscopic resection of the tumor that was found to glioblastoma². (*Id.*) Subsequently, the Appellant was treated with cranial irradiation 6300 rad and concurrent Temodar³ which was completed on October 17, 2016. (Exh. 5) Thereafter, the Appellant was on maintenance Temodar and alternating electric field therapy. (*Id.*) In February 2017 the Appellant developed left hand numbness/weakness and an MRI revealed recurrence in the right posterior frontal lobe near midline. (*Id.*) On March 9, 2017 the Appellant underwent a resection of the recurrent tumor. (*Id.*) The Appellant was then started on salvage therapy with Avastin. (*Id.*) The Appellant's most recent progress note contained in the record dated January 12, 2018 noted that her December MRI was excellent. (*Id.*)

At the lower levels, the Appellant submitted a letter to Contractor dated January 1, 2017 indicating that TTF was the Appellant's best option to treat her fatal disease. (Exh. 1, pp. 23-24) The Appellant noted that she began using Optune on November 21, 2016 and hopes the device will prevent recurrence and slow the rate of growth of the tumor. (*Id.*) The Appellant further noted that the Optune device is covered by numerous local and national insurance carriers. (*Id.*)

¹ The evidence submitted by the Appellant's representative has been admitted into the record pursuant to 42 C.F.R. § 405.1018(d)(2).

² **Glioblastoma (GBM)** is an aggressive type of cancer that can occur in the brain or spinal cord. GBM tumors form from cells called astrocytes that support nerve cells. GBM can occur at any age but tends to occur more often in older adults, and can cause worsening headaches, nausea, vomiting and seizures. GBM, also known as glioblastoma multiforme, can be very difficult to treat and a cure is often not possible. Treatments may slow progression of the cancer and reduce signs and symptoms (See Mayo Clinic at <https://www.mayoclinic.org/diseases-conditions/glioblastoma/cdc-20350148>).

³ **Temozolomide** (brand name: **Temodar**) is a chemotherapy drug used to treat GBM (See Chemocare at <http://chemocare.com/chemotherapy/drug-info/Temozolomide.aspx>).

The record contains two Optune Prescription Forms prescribing 6 months of Optune for the Appellant due to malignant neoplasm of frontal lobe (C71.1). (Exh. 2, pp. 11-13) Novocure issued invoices for the NOVO-TTF 100A in the amount of \$21,000 for each month dated September 21, 2017, October 21, 2017, November 21, 2017 and December 21, 2017. (Exh. 2, pp. 1-4) The Optune Service Agreement and delivery confirmation was signed by the Appellant on November 21, 2016. (Exh. 2, pp. 18-29) The Appellant also signed off on the patient information and consent. (Exh. 2, pp. 30-31)

The record contains a letter from Joel E. Kaiser Director of the Division of DMEPOS Policy confirming that the NovoTTF-100A system falls within the DME benefit category. (Exh. 2, p. 79)

A Letter of Medical Necessity dated January 30, 2017 was written by Dr. M.D. requesting coverage for Optune treatment. (Exh. 2, pp. 14-16) The letter indicated that Optune has been successfully used by selected patients and that the Appellant would be a good candidate for treatment. (*Id.*) An assessment of need was completed on November 2, 2016. (Exh. 2 p. 17)

National Comprehensive Cancer Network (NCCN) guidelines contained in the record indicate that alternating electric field therapy is a recommended course of treatment. (*See attached CD*; Exh. 5) Alternating electric field therapy (Optune) + adjuvant temozolomide is a NCCN category 2A (level 1 recommendation) recommendation following postoperative standard brain radiation therapy with concurrent temozolomide. (*Id.*)

The article from the Journal of the American Medical Association (JAMA) titled Maintenance Therapy with Tumor-Treating Fields Plus Temozolomide vs. Temozolomide Alone for Glioblastoma — A Randomized Clinical Trial describes the superior results in progression free survival as well as overall survival of glioblastoma patients using TTFields. (*See CD attached Exh 5*)

The Society of NeuroOncology organization conducted an internal, multicenter, prospective, randomized phase III trial in newly diagnosed GBM patients. (Exh. 2, p. 78) In the trial, after completion of radiotherapy with concomitant temozolomide (TMZ), patients were randomized (2:1) to adjuvant TMZ with NovoTTF or to adjuvant TMZ alone. (*Id.*) The study concluded that adjuvant TMZ chemotherapy and NovoTTF provided a clinically and statistically significant improvement in progression-free and overall survival, and should become the new standard of care against GBM. (*Id.*)

The Optune (NovoTTF-100A System) manual explained that Optune, for treatment of newly diagnosed and/or recurrent GBM, is a portable battery or power supply operated device which produces alternating electrical fields, called tumor treatment fields (“TTFields”), within the human body. (Exh. 2, pp. 53-77) Clinical data contained within the Optune (NovoTTF-100A System) manual notes that the results of a pivotal trial in newly diagnosed GBM showed that Optune/TMZ extends progression free and overall survival significantly compared to patients receiving TMZ alone. (*Id.*)

Optune received pre-market approval by the Food and Drug Administration (FDA) for recurrent glioblastoma in April of 2011 following positive results of a controlled trial. (Exh. 2, pp. 80-84) A phase III trial of Optune (NovoTTF-100A System) from Novocure was halted due to

statistically significant efficacy for the device in combination with chemotherapy to treatment newly diagnosed glioblastoma patients. (*See attached CD; Exh. 5*) Specifically, the trial was halted in order to offer the treatment to the remaining chemo-only group. (*Id.*) In 2015, Optune received pre-market approval by the FDA for newly diagnosed glioblastoma in combination with temozolomide after standard surgical resection and radiation therapy. (*See attached CD; Exh. 5*)

The record reflects that major insurance carriers such as Aetna, BCBS, Cigna, HealthPartners, Humana, United Healthcare, etc. have allowed for coverage for TTFT. (*See attached CD; Exh. 5*) The record also contains numerous in-depth peer-reviewed studies showing the effectiveness of the device. (*Id.*)

The record also contains a letter directed to Mr. Justin M. Kelly, RN BSN from Novocure regarding a reconsideration request for TTFT LCD coverage criteria. (*Exh. 5*) The letter indicates that currently the TTFT LCD includes language indicating that coverage for recurrent glioblastoma multiforme (GBM) is not reasonable and necessary; however coverage of newly diagnosed GBM is not addressed. (*Id.*) A final decision following the valid reconsideration request submitted was expected to be issued on September 18, 2018. (*Id.*)

At the hearing, counsel provided argument in support of the effectiveness of this device. (*Hearing CD*) Specifically, Ms. Parrish argued that the interim results of the clinical studies were so compelling that the data safety monitoring board recommended early termination to allow those who were not receiving treatment to crossover and receive the treatment. (*Id.*) Ms. Parrish also noted that the peer review literature was so effective that the device enjoys a level 1 recommendation, which signifies there is unanimous agreement among all of the experts based on the highest level of evidence that this treatment should be offered to individuals with glioblastoma. (*Id.*) Ms. Parrish further argued that quantification of effectiveness of a treatment is not a requirement for Medicare coverage, however if one were to measure the effects of the device, one should note that the Appellant has outlived the disease's life expectancy. (*Id.*)

Ms. Miles provided an overview regarding the Appellant's clinical history, course of treatment and current status. (*Id.*) Ms. Miles concluded that, among other things, the Optune device is the standard of care and treatment for glioblastoma at this time. (*Id.*)

Legal Framework

I. ALJ Review Authority **A. Jurisdiction**

An individual who, or an organization that is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services, provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. 42 C.F.R. § 405.1014; Social Security Act ("the Act") section 1869(b)(1)(A)). In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJ's within OMHA issue binding decisions of the Secretary, unless those decisions are later reviewed by the Medicare Appeals Council. (*Id.*)

For hearing requests filed on or after January 1, 2018, a party does not have a right to an ALJ hearing unless the remaining amount in controversy is \$160 after reduction for any Medicare payment already made and any applicable deductible and coinsurance amounts (42 CFR §405.1006(b) and (d)(1)(i)-(ii); *Federal Register*, Vol. 82, No. 188, Pg. 45592-45593, Sept. 29, 2017, effective January 1, 2018).

To be considered timely, the request for hearing must be received by OMHA within sixty days after the Appellant receives the reconsideration decision. 42 C.F.R. § 405.1002(a)(1). The Appellant is presumed to have received the QIC's reconsideration five days after the date noted on the first page of the reconsideration, unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3).

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the Appellant's favor. 42 C.F.R. § 405.1032(a) However, if evidence presented before or during the hearing causes the ALJ to question a fully favorable decision he or she will notify the Appellant and will consider it an issue at the hearing. 42 C.F.R. § 405.1032(b) The ALJ may decide a case on the record and not conduct an oral hearing if the Appellant and all the parties indicate in writing that they do not wish to appear before the ALJ at an oral hearing or if an examination of the record supports a finding in favor of the Appellant on every issue. 42 C.F.R. § 405.1038

Unless the ALJ dismisses the hearing, the ALJ will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. 42 C.F.R. § 405.1046(a) The decision must be based on evidence offered at the hearing or otherwise admitted into the record. (*Id.*) An Appellant may offer new evidence for the first time at the ALJ level of appeal only upon a showing of good cause why the evidence was not submitted to the QIC or a prior decision maker. 42 C.F.R. § 405.1018 The ALJ will determine whether good cause exists for the late submission of the new evidence and may only consider the evidence in making a decision if good cause is found. *See* 42 C.F.R. §§ 405.1018, 405.1028 and 405.1030. This late evidence restriction does not apply to unrepresented beneficiaries or to oral testimony given at a hearing. *See* 42 C.F.R. § 405.1018(d).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue and issues a decision based on the hearing record. 42 C.F.R. § 405.1000(d) and Section 557 of the Administrative Procedure Act. *De novo* review requires the ALJ to review and evaluate the evidence without regard to the findings of prior determinations on the claim and make an independent assessment relying upon the evidence and controlling laws. All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Act and applicable implementing regulations, are binding on ALJs. 42 C.F.R. § 405.1063.

The burden of proving each element of a Medicare claim lies with the Appellant by preponderance of the evidence. *See* Act §§ 1814(a)(1), 1815(b), and 1833(e); 42 C.F.R. § 424.5(a)(6), 405.1018, 405.1028, and 405.1030.

II. Principles of Law

A. Statutes and Regulations

Section 1831 of the Act establishes a supplementary insurance program for the aged and disabled. This insurance program, commonly referred to as Part B of Medicare, is financed through premium payments by enrollees together with contributions from funds appropriated by the Federal Government. §1831; 42 U.S.C. 1395j. The program allows for the reimbursement of physicians' services including surgery, consultation, and office visits. §1861(q); 42 U.S.C. 1395x(q)

The standard for payment of these services is found in section 1862(a)(1)(A) of the Act. There, the Act states that no payment may be made "...for items and services...[which] are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Section 1833(e) of the Act provides that payment will not be made unless sufficient information is furnished to determine the amounts due to the provider. *See also* 42 CFR §424.5(6).

Section 1862(a)(1)(A) of the Act provides that "[n]otwithstanding any other provision of the Act, no payment shall be made for any expenses incurred for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." *See also* 42 C.F.R. §411.15(k).

Section 1866(a)(1)(A)(i) of the Act provides that "[a]ny provider of services (except a fund designated for purposes of section 1814(g) and section 1835(e)) shall be qualified to participate under this title and shall be eligible for payments under this title if it files with the Secretary an agreement not to charge, except as provided in paragraph (2), any individual or any other person for items or services for which such individual is entitled to have payment made under this title (or for which he would be so entitled if such provider of services had complied with the procedural and other requirements under or pursuant to this title or for which such provider is paid pursuant to the provisions of section 1814(e)) of the Act." *See also* 42 C.F.R. §489.1 *et seq.* (setting forth the terms and limitations on provider agreements).

Section 1879 of the Act limits the liability of the Beneficiary and providers of services if the services are found to be not medically reasonable and necessary under Section 1862(a)(1)(A) or care was custodial in nature under Section 1862(a)(9) of the Act. Payment will only be made pursuant to this section if neither the Beneficiary nor the provider knew or could reasonably have been expected to know that the services were not covered. *See also* 42 C.F.R. §411.404; 42 C.F.R. §411.406.

B. Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than a National Coverage Determination (NCD), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for

coverage of selected types of medical items and services in the form of manuals and local medical review policies (LMRPs) or local coverage determinations (LCDs).

Section 1869(f)(1) of the Act provides that NCDs are binding upon Administrative Law Judges. *See also* 42 CFR §405.1060. *Medicare National Coverage Determinations Manual, Pub. 100-03, Ch. 1, sec. 280* ("NCD 280.1") provides a mandatory statement as to what constitutes equipment that meets the definition of DME, as follows:

"The term DME is defined as equipment which:

- * Can withstand repeated use; i.e., could normally be rented and used by successive patients;
- * Is primarily and customarily used to serve a medical purpose;
- * Generally is not useful to a person in the absence of illness or injury; and,
- * Is appropriate for use in a patient's home."

Section §1869(f)(2) of the Act provides that Administrative Law Judges will give substantial deference to LCDs, LMRPs, or CMS program guidance when applicable, and if they do not follow the policy they must explain why in their decision. *See also* 42 CFR §405.1062. The Local Coverage Determination Policy applicable to this case. The LCD at issue is L34823 and Policy Article 52711. LCD L34823 provides as follows:

Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on

Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

GENERAL

A Detailed Written Order (DWO) (if applicable) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed DWO, the claim shall be denied as not reasonable and necessary.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor

Policy Article 52711 provides in pertinent part as follows:

Code E0766 describes devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers.

This code is inclusive of all associated supplies necessary for the effective use of code E0766 including, but not limited to, transducers/surface electrodes, lead wires, adhesive patches, connectors, conductive gel and skin preps.

Medicare Benefit Policy Manual, Pub. 100-02 ("CMS Pub. 100-02"), Ch. 15, §110.1, also provides guidance pertaining to Medicare coverage of DME, and explains that

Expenses incurred by a beneficiary for the rental or purchases of durable medical equipment (DME) are reimbursable if the following three requirements are met:

- The equipment meets the definition of DME (§110.1);
- The equipment is necessary and reasonable for the treatment of the patient's illness or injury or to improve the functioning of his or her malformed body member (§110.1); and
- The equipment is used in the patient's home.

Ch. 15, §110.1(A) further explains as follows:

- Equipment which is primarily and customarily used for a nonmedical purpose may not be considered "medical" equipment for which payment can be made under the medical insurance program. This is true even

though the item has some remote medically related use. For example, in the case of a cardiac patient, an air conditioner might possibly be used to lower room temperature to reduce fluid loss in the patient and to restore an environment conducive to maintenance of the proper fluid balance. Nevertheless, because the primary and customary use of an air conditioner is a nonmedical one, the air conditioner cannot be deemed to be medical equipment for which payment can be made.

- Other devices and equipment used for environmental control or to enhance the environmental setting in which the beneficiary is placed are not considered covered DME. These include, for example, room heaters, humidifiers, dehumidifiers, and electric air cleaners. Equipment which basically serves comfort or convenience functions or is primarily for the convenience of a person caring for the patient, such as elevators, stairway elevators, and posture chairs, do not constitute medical equipment. Similarly, physical fitness equipment (such as an exercycle), first-aid or precautionary-type equipment (such as preset portable oxygen units), self-help devices (such as safety grab bars), and training equipment (such as Braille training texts) are considered nonmedical in nature.

Medicare Program Integrity Manual, Pub. 100-08, ("CMS Pub. 100-08"), Ch. 5, provides guidance as to documentation for DME claims, including the requirement of both physician orders for DME and supporting documentation for medical necessity and delivery. Ch. 5, also provides guidance as to patient documentation requirements to support that Medicare coverage criteria for items of DME have been met.

For any DMEPOS [Durable Medical Equipment Prosthetics Orthotics and Supplies] item to be covered by Medicare, the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the patient's diagnosis and other pertinent information including, but not limited to, duration of the patient's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc. . . . neither a physician's order nor a CMN [certificate of medical necessity] . . . nor a supplier prepared statement nor a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier. There must be information in the patient's medical record that supports the medical necessity for the item and substantiates the answers on the CMN (if applicable) . . . or information on a supplier prepared statement or physician attestation (if applicable). . . . The patient's medical record is not limited to the physician's office records. It may include hospital, nursing home, or HHA records and records from other health care professionals. *CMS Pub. 100-08, Ch. 5, §5.7.*

Medicare Program Integrity Manual, Pub. 100-08 ("CMS Pub. 100-08"), Ch. 13, §13.5.1 explains the reasonable and necessary provisions in LCDs as follows:

Contractors shall describe in the draft LCD the circumstances under which the item or service is reasonable and necessary under 1862(a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
 - Furnished in a setting appropriate to the patient's medical needs and condition;
 - Ordered and furnished by qualified personnel;
 - One that meets, but does not exceed, the patient's medical need; and
 - At least as beneficial as an existing and available medically appropriate alternative.

Analysis

The QIC denied coverage on the basis that there was insufficient documentation to quantify the effects of the device for this beneficiary. (Exh. 1, pp. 4-11) The QIC held that currently published studies in the medical literature do not clearly document the effectiveness of this device. (*Id.*) According, based on the available documentation, the requirements outline in the LCD, NCD, PIM, and IOM have not been met. (*Id.*) The QIC further held Novocure liable for the denied charges. (*Id.*)

At the hearing, Ms. Parrish provided argument in support of the effectiveness of the device and further argued that quantification of effectiveness of a treatment is not a requirement for Medicare coverage. The undersigned agrees with the Appellant's position.

Local Coverage Determination L34823, promulgated by Medicare Contractors CGS Administrators, LLC and Noridian Healthcare Solutions, LLC, which became effective January 1, 2017 and as currently in effect, states that "Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary⁴." Pursuant to 42 C.F.R. § 405.1062(a) an ALJ is not bound by contractor LCDs or CMS program guidance, such as program memoranda and manual instructions, "but will give substantial deference to these policies if they are applicable to a particular case." An ALJ must explain the reason for not following such a policy in a specific case. 42 C.F.R. § 405.1062(b). Any decision to disregard a policy "applies only to the specific claim being considered and does not have precedential effect." (*Id.*)

In the instant appeal, the Appellant, _____ a then 70 year old male female presented to the hospital on July 24, 2016 with complaints of dropping things out of her left hand. (Exh. 2, pp.

⁴ The undersigned notes that LCD L34823 does not articulate the reason the Contractor has determined categorically that the device is not reasonable and necessary.

34-36) Specifically, the Appellant first noticed the difficulty with hand strength approximately 2 weeks prior to her presentation and the symptoms persisted and progressed. (*Id.*) She ultimately felt more weakness in the left hand and came to the emergency department. (*Id.*) A CT scan of the head showed a right sided brain lesion 4 x 4.5 cm. (*Id.*) An brain MRI taken on July 25, 2016 showed a right posterior frontal lobe 4.8 x 4.5 x 5.0 cm cystic mass with a mild amount of vasogenic edema. (*Id.*) The Appellant then underwent a stealth guided stereofactic craniotomy with microscopic resection of the tumor that was found to glioblastoma. (*Id.*) Subsequently, the Appellant was treated with cranial irradiation 6300 rad and concurrent Temodar which was completed on October 17, 2016. (Exh. 5) Thereafter, the Appellant was on maintenance Temodar and alternating electric field therapy. (*Id.*) In February 2017 the Appellant developed left hand numbness/weakness and an MRI revealed recurrence in the right posterior frontal lobe near midline. (*Id.*) On March 9, 2017 the Appellant underwent a resection of the recurrent tumor. (*Id.*) The Appellant was then started on salvage therapy with Avastin. (*Id.*) The Appellant's most recent progress note contained in the record dated January 12, 2018 noted that her December MRI was excellent. (*Id.*)

After a careful and thorough review of Appellant's arguments and the evidence in the record, the undersigned has declined to follow the applicable LCD in light of FDA approval, acceptance by major insurance carriers, peer-reviewed medical literature, general acceptance by the medical community and the specific evidence of medical necessity in this case. Specifically, in this regard the Appellant submitted documentation confirming the pre-market approval by the FDA for recurrent glioblastoma in April of 2011 following positive results of a controlled trial and later pre-market approval in October 2015 for newly diagnosed glioblastoma in combination with temozolomide after standard surgical resection and radiation therapy.

The Appellant also submitted an article from the Journal of the American Medical Association (JAMA) titled Maintenance Therapy with Tumor-Treating Fields Plus Temozolomide Vs. Temozolomide Alone for Glioblastoma — A Randomized Clinical Trial and the National Comprehensive Cancer Network (NCCN) guidelines. The article describes the superior results in progression free survival as well as overall survival of glioblastoma patients using TTFields; while the National Comprehensive Cancer Network (NCCN) guidelines show that alternating electric field therapy is a recommended course of treatment for glioblastoma. Specifically, alternating electric field therapy (Optune) + adjuvant temozolomide received a NCCN category 2A (level 1) recommendation following postoperative standard brain radiation therapy with concurrent temozolomide. Additionally, the record contains numerous payer policies for TTFT from major insurance carriers, including but not limited to, Aetna, BCBS, Cigna, HealthPartners, Humana, United Healthcare and in-depth peer-reviewed studies showing the effectiveness of the device.

Furthermore, the medical records reflect that the use of the Optune device has made a meaningful contribution to the treatment of the Appellant's glioblastoma. The undersigned notes that the Appellant suffers from an orphan disease with limited treated options and that Optune in combination with temozolomide has been medically necessary and appropriate in this case. Specifically, the record reflects that the Appellant is stable as the most recent progress note contained in the record indicates the Appellant's MRI was excellent.

Based on the foregoing, the undersigned finds that the E0766 (electrical stimulation device used for cancer treatment) furnished to the Appellant on September 21, 2017, October 21, 2017,

November 21, 2017 and December 21, 2017 by Novocure (Provider/Supplier) was medically reasonable and necessary and is covered by Medicare.

Conclusions of Law

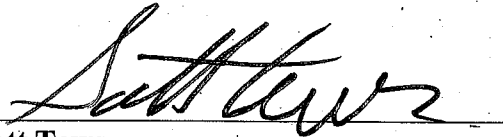
Medicare coverage exists for the E0766 (electrical stimulation device used for cancer treatment) provided to the Appellant on September 21, 2017, October 21, 2017, November 21, 2017 and December 21, 2017.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED

Dated: **DEC 19 2018**

A handwritten signature in black ink, appearing to read "Scott Tews", is written over a horizontal line.

Scott Tews
U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Irvine, CA

Appeal of:	OMHA Appeal No.: 1-7832341075
Beneficiary:	Medicare Part: B
Medicare No.:	Before: Sharon L. Turner Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record and at the hearing, an **FULLY FAVORABLE** decision is entered for the Beneficiary and Appellant, (Appellant).

PROCEDURAL HISTORY

The Appellant submitted a claim for an Optune tumor treatment field therapy device (E0766) supplied by Novocure (Provider) on August 9, 2017, September 9, 2017, and October 10, 2017. Upon initial determination, Medicare denied payment on the claim. The Appellant filed an appeal of the denial with CGS Administrators, LLC, the Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) with jurisdiction over the claim. The MAC upheld the denial on the ground that the item was not covered by Medicare, as currently published studies in the medical literature did not clearly document the effectiveness of the device. The MAC found the Provider liable for the non-covered item. (Exh. 1, pp. 47-49).

The Appellant then filed a request for reconsideration with C2C Solutions, Inc., the DME Qualified Independent Contractor (QIC). The QIC affirmed the denial, reasoning that the medical documentation did not support a need for the device. The QIC found the Appellant liable for the denied item. (Exh. 1, pp. 1-6).

The Appellant's request for hearing before an Administrative Law Judge (ALJ) was timely filed. (Exh. 3). The Provider also filed a request for hearing. (Exh. 3, pp. 18-20). The amount in controversy meets the jurisdictional requirement for a hearing before the Office of Medicare Hearings and Appeals (OMHA). (42 C.F.R. § 405.1006).

Due notice was provided, and a telephonic hearing was held in Irvine, California on October 9, 2018. The Appellant appeared at the hearing with her representative, Debra Parrish, Esq. The Provider waived notice and legal representation, and appeared as a party through its representatives, Dan McCoy, Julie Miles, R.N., and Tim Parks. Exhibits 1 through 5 were admitted into the record without objection.

ISSUES

1. Whether Medicare Part B payment can be made for the Optune tumor treatment field therapy device (E0766) supplied to the Appellant on August 9, 2017, September 9, 2017, and October 10, 2017.
2. Whether payment can otherwise be made to the Provider or Appellant pursuant to Section 1879 of the Act if it is determined that the item is not medically reasonable and necessary.

FINDINGS OF FACT

The record establishes the following facts by a preponderance of the evidence:

1. During the dates of service, the Appellant was a 71-year-old female. She had a medical history significant for right occipital glioblastoma, malignant neoplasm of the brain, hypertension, and gastroesophageal reflux disease (GERD). (Exh. 2, pp. 25-26).
2. On January 4, 2017, the Appellant was diagnosed right occipital glioblastoma multiforme (GBM) and underwent a craniotomy. (Exh. 2, p. 25).
3. On March 22, 2017, the physician signed and dated a prescription for Optune, a tumor treating field therapy (TTFT) device, for six months. The diagnosis was right occipital GBM (C71.9). The preferred treatment start date was March 4, 2017. (Exh. 2, p. 8).
4. On June 15, 2017, the Beneficiary had a neuro-oncology follow up visit. She had started the Optune TTFT device one and a half months earlier and was tolerating the device well. (Exh. 2, p. 26).
5. On July 13, 2017, the Appellant had a neuro-oncology visit to follow up on newly diagnosed right occipital GBM. After undergoing a craniotomy, the Appellant underwent concurrent chemo-radiation therapy with temozolomide and three cycles of adjuvant temozolomide chemotherapy, which she completed in June 2017. A brain MRI showed an enhancing mass in the posterior aspect of the right cerebral hemisphere and peritumoral FLAIR signal abnormality that were not significantly changed from the most recent study. The neuro-oncologist reviewed the MRI with the Appellant and indicated that the tumor site was stable compared to the previous

month's image. The plan was to continue using the Optune device for TTFT treatment, continue adjuvant temozolomide chemotherapy, hold the next cycle of temozolomide given the Appellant's low platelet count, and obtain a repeat brain MRI and perfusion study in two months. (Exh. 2, pp. 25-30).

6. On July 18, 2017, the Appellant's physician submitted a letter in support of the use of the Optune device to treat the Appellant's GBM. The physician noted that the Optune device uses TTFT to inhibit cancer cell replication. The Optune device was FDA-approved for newly diagnosed GBM when used in combination with temozolomide after standard surgical resection and combined radiation and chemotherapy. Furthermore, alternating electric field therapy, such as Optune, and adjuvant temozolomide is a National Comprehensive Cancer Network (NCCN) Category 2a recommendation following postoperative standard brain radiation therapy with concurrent temozolomide. (Exh. 2, p. 10).
7. On September 25, 2017, the physician signed and dated another prescription for Optune for a period of six months. The diagnosis was GBM (C71.9). (Exh. 2, p. 7).
8. On August 7, 2018, the MAC wrote a letter to the Provider to clarify that the LCD's denial of coverage of TTFT applied only to recurrent GBM and did not address coverage of newly diagnosed GBM. The DME MAC Medical Directors reviewed recent peer-reviewed literature and NCCN guidelines and determined that a request for coverage of TTFT to treat newly diagnosed GBM is a valid request. (Exh. 5, pp. 7-9).

LEGAL FRAMEWORK

I. ALJ Review Authority

A. *Jurisdiction*

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services, provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. (Social Security Act (Act) § 1869(b)(1)(A)).

In implementing this statutory directive, the Secretary has delegated his authority to administer the nationwide hearings and appeals system for the Medicare program to the Office of Medicare Hearings and Appeals (OMHA). The administrative law judges (ALJs) within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. (70 Fed. Reg. 36386, 36387 (June 23, 2005)).

For requests made in 2018, a hearing before an ALJ is available only if the remaining amount in controversy is \$160.00 or more. (42 C.F.R. § 405.1006; 82 Fed. Reg. 45592 (Sep. 29, 2017)). The request for hearing is timely if filed within sixty (60) days of receipt of the notice of the QIC's reconsideration decision. (42 C.F.R. § 405.1002(a)(1)).

B. Scope of Review

The issues before the ALJ include all the issues for the claims or appealed matter specified in the request for hearing that were brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. (42 C.F.R. § 405.1032(a)).

C. Standard of Review

OMHA is staffed with ALJs who conduct de novo hearings. (See 42 C.F.R. § 405.1000(d)). An ALJ qualified and appointed pursuant to the Administrative Procedure Act acts as an independent finder of fact in conducting a hearing pursuant to section 1869 of the Act. This requires de novo consideration of the facts and law.

II. Principles of Law

A. Statutes and Regulations

Title XVIII of the Act, as amended (42 U.S.C. § 1395 *et seq.*), establishes a federally subsidized health insurance program (Medicare) to be administered by the Department of Health and Human Services (HHS). The Supplementary Medical Insurance program (Part B of Title XVIII of the Act) provides coverage for a variety of medical and other health services furnished by physicians and for a number of other specific health-related items and services. (Act § 1832(a); *see also* 42 C.F.R. § 410.3). Individuals participate voluntarily in the Medicare Part B program and pay a monthly premium. (Act § 1831; *see also* 42 C.F.R. § 407.2).

Section 1862(a) of the Act limits Medicare payments to those items or services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member," notwithstanding any other provision of the Act. (See *also* 42 C.F.R. § 411.15(k)(1)). Section 1833(e) of the Act requires a claim for payment to be supported by sufficient information. (See *also* 42 C.F.R. § 424.5(a)(6)). An item of durable medical equipment may require a written physician order pursuant to Section 1834(a)(11)(B) of the Act. Title 42 C.F.R. Section 410.38(g) further provides that CMS may determine through carrier instructions, or a carrier may determine, that an item of durable medical equipment requires a written physician order before delivery of the item.

Section 1832(a)(1) of the Act permits payment for "medical and other health services" as a Part B benefit. "Durable medical equipment" is a component of "medical and other health services" as defined by the Act. (Act § 1861(s)(6); *see also* 42 C.F.R. § 410.10(h)). Specifically, "**durable medical equipment**" is defined as:

[E]quipment, furnished by a supplier or a home health agency that—

- (1) Can withstand repeated use;
- (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years;
- (3) Is primarily and customarily used to serve a medical purpose;
- (4) Generally is not useful to an individual in the absence of an illness or injury; and
- (5) Is appropriate for use in the home. (42 C.F.R. § 414.202).

B. Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than a National Coverage Determination (NCD), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. (*See also* 42 C.F.R. § 405.860). NCDs promulgated by the Secretary of HHS under the authority of Section 1862(a)(1) of the Act dictate the criteria under which Medicare covers specified services, procedures or supplies. NCDs are binding upon ALJs. (42 C.F.R. § 405.732(a)(4)). “An ALJ may not disregard, set aside or otherwise review an NCD.” (42 C.F.R. § 405.732(b)(1)).

In lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for Medicare coverage of selected types of medical items and services on a carrier-wide basis in accordance with Section 1862(a)(1)(A) of the Act (i.e., a determination as to whether the service is medically reasonable and necessary) in the form of manuals and local medical review policies (LMRPs) or local coverage determinations (LCDs). Although LMRPs and LCDs are not binding on an ALJ in adjudicating a claim, the regulations require that the policies be afforded “substantial deference” and any departure therefrom be explained in the resulting decision. (42 C.F.R. § 405.1062 (applicability of LCDs and other policies not binding on the ALJ and MAC)). An ALJ decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.

The MAC has promulgated an LCD for Tumor Treatment Field Therapy (TTFT) (L34823), which provides that “Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.” (L34823).

ALJs may give consideration to the manuals issued by the CMS in determining benefit coverage and eligibility. Although not binding on the ALJ, the respective manuals provide guidance in the administration of the Medicare program. (*Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87 (1995)).

C. Limitation of Liability

Section 1879 of the Act provides that when Medicare excludes payment and coverage pursuant to Section 1862, as well as 1814(a)(2)(C), and 1835(a)(2)(A) which establish Medicare coverage for home health services, payment may nevertheless be made for the items or services, if neither the beneficiary nor the provider or supplier knew, or could not reasonably be expected to have known, that the items or services would not be covered or payable by Medicare.

For the purposes of establishing liability under Section 1879 of the Act, a provider or supplier will be considered to have known that items or services would not be covered or payable by Medicare if: (1) it was given notice that the same or similar services were not covered by CMS or any of its agents (including intermediaries and carriers), by utilization review committees, or by the beneficiary’s attending physician; (2) prior to service, it informed the beneficiary that the services are not covered by Medicare or the beneficiary no longer needed covered services; or (3) it is clear that it could have been expected to have known from its receipt of notices from

CMS or its agents, Federal Register publications, or based on its “knowledge of what are considered acceptable standards of practice by the local medical community.” (42 C.F.R. § 411.406(b)-(e)).

ANALYSIS

This appeal concerns whether Medicare payment can be made for the TTFT device (E0776) that were supplied to the Appellant on August 9, 2017, September 9, 2017, and October 10, 2017.

The QIC affirmed the denial, reasoning that the item at issue is not medically reasonable and necessary. Specifically, the medical documentation did not support the need for the device and there was insufficient documentation to quantify the effects of the device. The currently published studies in the medical literature do not clearly document the effectiveness of the device. Furthermore, LCD L34823 provides that TTFT (E0766) will be denied as not reasonable and necessary. Thus, Medicare coverage criteria were not met.

The Appellant maintains that the Optune TTFT device is medically reasonable and necessary. Specifically, the Appellant is a 72-year-old female who was diagnosed with GBM in January 2017. Her clinician prescribed concurrent chemotherapy and radiation in addition to Optune to treat her GBM after surgery. The Appellant started using Optune in May 2017. The documentation supports the Appellant’s diagnosis of GBM and need for the Optune device. An exact quantification of effectiveness is not a requirement for Medicare coverage. Given the Appellant’s limited treatment options, clinical studies regarding the effectiveness of the Optune device, professional societies’ statements and policies, and FDA approval, the ALJ should not defer to the LCD in this case. (Exh. 5, pp. 2-5). At the hearing, the Appellant’s representative argued that Medicare coverage is based upon peer-reviewed literature, the consensus of experts, and whether the treatment has been accepted by the community. In this case, numerous peer-reviewed articles were published stating that the Optune TTFT device is safe and effective. The results of a clinical trial that showed the effectiveness of Optune for newly diagnosed GBM was so compelling that the FDA agreed to terminate the trial early to make the treatment available to non-trial participants. Because the clinical literature was so compelling, the NCCN rendered a unanimous decision that Optune should be offered to individuals with newly diagnosed GBM. The Optune TTFT device is widely accepted because it has been prescribed in all 50 states and is covered by all major insurers nationwide. In addition, the MAC indicated that the LCD that denies coverage of TTFT does not apply to instances of newly diagnosed GBM. The Appellant testified that since using the Optune TTFT device, she had had no new GBM on her MRIs, which she receives every two months. The Appellant currently goes to the gym three times per week and has felt well enough to travel on cruises and to her grandchildren’s graduation ceremonies. The Provider’s representative argued that the life expectancy of a patient with GBM is 10 months without using the Optune TTFT device. The Appellant has far exceeded this life expectancy. Furthermore, since the Appellant started using the Optune TTFT device, she has had no progression or recurrence of GBM. Thus, the Optune TTFT device is medically reasonable and necessary to treat the Appellant’s newly diagnosed GBM.

The applicable LCD provides that “[t]umor treatment field therapy (E0766) will be denied as not reasonable and necessary.” (L34823). However, LCDs are not binding on an ALJ in adjudicating a claim. Although an LCD should be afforded “substantial deference,” any departure from the LCD should be explained in the resulting decision. (42 C.F.R. § 405.1062).

In this particular case, the Appellant is entitled to Medicare coverage of the Optune TTFT device to treat her newly diagnosed GBM. Although the LCD denies Medicare coverage for TTFT, the MAC concedes that the LCD is not applicable to newly diagnosed GBM. Rather, in light of recent peer-reviewed articles supporting the effectiveness of TTFT on newly diagnosed GBM, the MAC determined that a request for Medicare coverage of TTFT to treat newly diagnosed GBM is valid. (Exh. 5, pp. 7-9). Even if the LCD does apply to cases involving newly diagnosed GBM, LCDs are not binding on ALJs. In this case, there is sufficient evidence to support a departure from the LCD. Specifically, the Appellant was diagnosed with GBM in January 2017. (Exh. 2, p. 25). On March 22, 2017, the Optune TTFT device was prescribed to the Appellant after she had undergone surgery, concurrent chemoradiation therapy, and several cycles of temozolomide chemotherapy to treat her newly diagnosed GBM. After using the Optune TTFT device for several months, the July 13, 2017 MRI indicated that the Appellant’s tumor site was stable. (Exh. 2, pp. 8, 25-30). As of the date of the hearing, the Appellant has had no progression or recurrence of GBM. (Testimony). Given the above considerations, the Optune TTFT device is medically reasonable and necessary to treat the Appellant’s newly diagnosed GBM.

Thus, Medicare coverage is warranted for the Optune TTFT device supplied by the Provider on August 9, 2017, September 9, 2017, and October 10, 2017.

CONCLUSIONS OF LAW

The Appellant is entitled to Medicare coverage for the Optune TTFT device (E0776) supplied by the Provider on August 9, 2017, September 9, 2017, and October 10, 2017. The issue of liability is moot as this is a fully favorable decision.

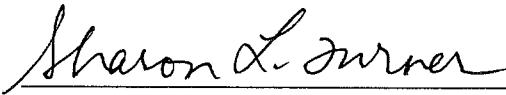
ORDER

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

OCT 10 2018

Dated: _____


 Sharon L. Turner
 Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Cleveland Field Office
Cleveland, Ohio

Appeal of:	ALJ Appeal No.: 1-8067095388
Beneficiary:	Medicare Part B
HICN:	Before: Thomas S. Tyler U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, a **FULLY FAVORABLE** on-the-record decision is entered for the Beneficiary.

Procedural History

Novocure, the provider, submitted claims to Medicare for tumor treatment field therapy (TTFT) it provided to the Beneficiary from December 28, 2017 to March 28, 2018. The claims were denied initially and upon reconsideration. The matter was then forwarded to C2C Solutions, Inc., a qualified independent contractor (QIC), which issued an unfavorable decision on October 25, 2018 and found the provider liable for payment of the non-covered services.

The Office of Medicare Hearings and Appeals (OMHA) received the Appellant's timely filed appeal. The remaining amount in controversy meets the jurisdictional requirements for a hearing before OMHA.

A telephone hearing in this matter was scheduled for January 3, 2019 at 10:30 AM EST in Cleveland, Ohio before the undersigned ALJ. The Appellant indicated its intention to participate. The Medicare contractors were provided notice of the date and time of the hearing but did not indicate any intention to participate. While reviewing the case for hearing, the undersigned ALJ determined that all of the issues are appropriately resolved in the Beneficiary's favor. A hearing was not conducted and a decision on-the-record has been entered in accordance with 42 C.F.R. §405.1000(g) and §405.1038. All exhibits were entered into the record and have been considered in making this decision.

Issue

The issue is whether the tumor treatment field therapy (TTFT) provided to the Beneficiary from December 28, 2017 to March 28, 2018 is covered under Medicare Part B. If the items are not covered under Medicare, a second issue is who is responsible for the non-covered charges.

Findings of Fact

The Beneficiary in this case is a 66 year-old man who was diagnosed with stage IV glioblastoma in June 2017. His physician prescribed the Optune system (E0766) in addition to concurrent chemotherapy and radiation. Unfortunately, because of his multifocal disease, surgical resection of the lesions was not a treatment option. Optune, previously known as the NovoTTF-100A System, is durable medical equipment that delivers alternating electric fields or tumor treating fields to the brain. The device consists of an electric field generator which is connected to four insulated transducer arrays. The arrays are placed on the patients scalp and deliver the tumor treating fields therapy (TTFT) to the patient's glioblastoma. The tumor treating fields interfere with the proliferation of malignant cells. It is locally or regionally delivered using alternating electric fields to prevent the rapid cell division ordinarily exhibited by cancer cells.

He began treatment with TTFields on September 28, 2017 and has had very good results. (Exhibit 2, pg. 10; Beneficiary's Pre-hearing Brief). The physician signed a prescription form on December 7, 2017 for Optune. (*Id.* at pgs. 22-12).

The record contains multiple articles regarding treatment of glioblastoma and the use of the Optune system. (Exhibit 2).

The Appellant argued in briefs that Optune is included in the National Comprehensive Cancer Network guidelines for recurrent glioblastoma and for newly diagnosed glioblastoma and that it is a Food and Drug Administration approved treatment of this type of cancer.

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) § 1869(b)(1)(A).

In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *Id.*

A hearing before an ALJ is only available if the remaining amount in controversy is \$160 or more. *See* 76 Fed. Reg. 59138 (Sept. 23, 2011) and 42 C.F.R. §405.1006(b)(2). The request for hearing is timely if filed within sixty days from the date the party receives notice of the QIC's reconsideration. *See* 42 C.F.R. § 405.1014(b)(1).

B. Scope of Review

Under the implementation policy of the Centers for Medicare and Medicaid Services, United States Department of Health and Human Services, all appeal requests stemming from a QIC reconsideration are governed by the Administrative Law Judge Hearing Procedures outlined in 42 C.F.R. §§ 405.1000 – 1018. 70 Fed. Reg. 11425 (March 8, 2005).

The issues before the administrative law judge include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the party's favor. However, if evidence presented before the hearing causes the administrative law judge to question a favorable portion of the determination, the administrative law judge will notify the parties before the hearing and may consider it an issue at the hearing. 42 C.F.R. § 405.1032(a).

C. Standard of Review

The Office of Medicare Hearings and Appeals is staffed with Administrative Law Judges who conduct de novo hearings. 42 C.F.R. § 405.1000(d).

II. Principles of Law

A. Statutes and Regulations

The Medicare program, Title XVIII of the Social Security Act (the Act), is administered through the Centers for Medicare and Medicaid Services (CMS), a component of the United States Department of Health and Human Services (HHS). Under the authority of Section 1842(a) (1) (A) of the Act, the Secretary of HHS is authorized to enter into contracts with private entities for the day-to-day operations of the program.

Part B of Title XVIII, the Supplementary Medical Insurance program, provides coverage for a variety of medical services and supplies furnished by physicians, or by others in connection with physicians' services, for outpatient hospital services, and for a number of other specific health-related items and services. Individuals participate voluntarily in the Medicare Part B program and pay a monthly premium.

Sections 1832(a)(2)(B), 1861(s)6), and 1862(a)(1)(A) of the Act provide that Part B covers durable medical equipment (DME) that is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII, § 1833(e) of the Act provides that no payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may

be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

Title XVIII, § 1861 of the Act addresses prosthetic devices as follows:

(s) The term “medical and other health services” means any of the following items or services:

- (8) prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens;
- (9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition.

B. Medicare Manual System

Administrative Law Judges may also give consideration to the manuals and rulings issued by the CMS in determining benefit coverage and eligibility. Although not binding on the Administrative Law Judge, the respective manuals provide guidance in the administration of the Medicare program. (*Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87 (1995)).

Section 1871(a)(2) of the Act provides that no rule, requirement or statement of policy, other than a National Coverage Determination (“NCD”), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program unless it is promulgated as a regulation by CMS. However, although not subject to the force and effect of the law, CMS and its contractors, have issued policy and guidelines, including Local Coverage Determinations (LCD’s) that describe criteria for coverage for selected types of medical services and supplies. NCDs promulgated by the Secretary of HHS under the authority of § 1862(a)(1) of the Act dictate the criteria under which specified services, procedures or supplies are covered by Medicare. NCDs are binding upon ALJs. 42 CFR §405.732(a)(4). “An ALJ may not disregard, set aside or otherwise review an NCD.” (42 CFR §405.732(b)(1)).

There is no NCD specific to tumor treatment field therapy. However, there is a local coverage determination that can be found at L34823. Local Coverage Determination, L34823 addresses tumor treatment field therapy (TTFT). It states:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

For an item to be covered by Medicare, a detailed written order (DWO) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed DWO, the item will be denied as not reasonable and necessary.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

A4555 ELECTRODE/TRANSDUCER FOR USE WITH ELECTRICAL STIMULATION DEVICE USED FOR CANCER TREATMENT, REPLACEMENT ONLY

E0766 ELECTRICAL STIMULATION DEVICE USED FOR CANCER TREATMENT, INCLUDES ALL ACCESSORIES, ANY TYPE

However, policy article A52711 provides that tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement, the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Code E0766 is in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories. Separate billing of supplies and/or accessories will be denied as unbundling.

Analysis

At issue in this case is whether reimbursement can be made for the TTFT therapy provided to the Beneficiary from December 28, 2017 to March 28, 2018.

The Local Coverage Determination that addresses TTField Therapy, L34823, specifically denies coverage. Without explanation, it states that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. The LCD does not provide any circumstances under which TTField therapy would be covered.

The Beneficiary in this case has glioblastoma and was given a prescription by his treating physician to use both TTField therapy and concurrent chemotherapy and radiation. The Appellant notes that it understands that there is an LCD that states that TTField Therapy is not medically reasonable and necessary but noted that the last revision of the LCD L34832 was in 2013. The Beneficiary explained that the Optune therapy system that is at issue in this case was FDA approved for treatment of glioblastoma.

While we acknowledge that the Medicare contractors appropriately considered LCD L34832 in making the decision to deny the TTField Therapy in this case based upon the unambiguous pronouncement that “tumor treatment field therapy (E0766) will be denied as not reasonable and necessary,” we decline to follow that statement in the LCD. The Code of Federal Regulations identify the applicability of Local Coverage Determinations. It states that LCDs are required to be adhered to by Medicare contractors. (42 C.F.R. §405.1062). However, Administrative Law Judges and the Medicare Appeals Council are not bound by LCDs. If an ALJ declines to follow an LCD in a particular case, he or she may do so, but must explain why the policy was not followed. (*Id.*).

In this case, LCD L34832 says that TTField therapy will be denied as not reasonable and necessary but it does not provide any justification for that statement. The treatment that the Beneficiary is seeking is called “Optune.” “Optune is a portable battery or power supply operated device which produces alternating electrical fields, called tumor treatment fields (TTFields) within the human body. The TTFields are applied to the patient’s shaved head by means of electrically insulated surface transducer arrays, such that resistively coupled electric currents are not delivered to the patient. The TTFields disrupt the rapid cell division exhibited by cancer cells.” https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034S013b.pdf.

We conclude that the LCD at issue in this case has been overcome by recent medical advancements, studies and FDA conclusions regarding the demonstrated therapeutic benefits of the Optune technology. When the language was first placed in the LCD, it is likely that TTField Therapy was an emerging technology that was not fully recognized as an effective treatment of this particular brain cancer. However, at around the same time of the last LCD update, there were studies conducted and the results published passing on the efficacy of the use of TTField therapy, most notably the Optune (NovoTTF-100A therapy), for recurrent and new diagnoses of glioblastoma. *Stupp et al., NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma: a randomized phase III trial of a novel treatment modality.* Eur J Cancer. 2012 Sep; 48(14):2192-202. The results of further studies were presented recently in the Annual Meeting of the American Association for Cancer Research. *Stupp, Hegi, Ibdaih, et al. Tumor treating fields added to standard chemotherapy in newly diagnosed glioblastoma (GBM): final results of a randomized, multicenter phase III trial,* Program and Abstracts of the 2017 Annual Meeting of the American Association for Cancer Research April 1-April 5, 2017 Washington, D.C. Abstract LBA AACR CT007. The results of these studies determined that Optune in

combination with temozolomide was an effective treatment of this particular brain cancer, whether newly diagnosed or recurrent, that resulted in significant improvement in life expectancy of most patients. Moreover, Optune was approved by the FDA for use in the treatment of newly diagnosed glioblastoma on October 5, 2015¹.

Moreover, the National Comprehensive Cancer Network (NCCN) is a non-profit alliance of 28 leading cancer centers dedicated to patient care, research and education regarding many different cancers. (<http://www.nccn.org>). In 2018 updated its clinical practice guidelines to designate alternating electric field therapy (Optune) in conjunction with temozolomide as a category 1 treatment recommendation for patients who were newly diagnosed with glioblastoma following maximum tumor resection and radiation therapy.

The advancement of medical science can sometimes outpace the reimbursement provisions provided in an LCD. In this case, that is exactly what has happened. To determine reimbursement in this case, we find the more applicable guidance is that found in the provisions of the Medicare Program Integrity Manual (CMS Pub. 100-08) (MPIM) which provides guidance for determining coverage for medical items and services in LCDs. (MPIM, Ch. 13 at §13.5.4). Under that CMS guidance, items or services that are medically reasonable and necessary, safe and effective, not experimental or investigational and appropriate for the treatment of the medical condition should be covered in an LCD. (*Id.*). The FDA premarket approval, recent studies identified above and NCCN guidelines check all the boxes indicating that Optune is medically reasonable and necessary, safe and effective, not experimental or investigational and appropriate for the treatment of the Beneficiary's medical condition.

We are also persuaded by the Beneficiary's medical provider and Beneficiary himself. The Beneficiary's physician prescribed the treatment at issue in this case and explained to the Beneficiary that there are few other promising treatment options. (Exhibit 2, p. 10, 26). The Beneficiary noted that every few months he has an MRI to determine the growth of his cancer and the past three MRIs have shown no growth. (*Id. at p. 10*). The Beneficiary's own experience supports the findings of the studies.

On the basis of the foregoing, we find that the recent FDA approval of the efficacy of Optune in the treatment of glioblastoma, the studies that have found medical efficacy to the use of the treatment, the NCCN guidelines that have been updated to include Optune and the use of the treatment by the Beneficiary's experienced radiation oncologist all cause us to decline to follow the statement in the LCD that tumor treatment field therapy will be denied as not reasonable and necessary. The conclusion in the LCD has been overcome by facts and circumstances that indicate that the treatment is both medically reasonable and necessary. No explanation was provided by the LCD for the failure to cover the TTField therapy and overwhelming medical evidence indicates the treatment has been and will continue to be effective for this Beneficiary.

Consequently, the undersigned finds that the Medicare requirements have been met. Accordingly, the ALJ finds that the TTFT treatment provided to the Beneficiary in this case are covered under Medicare Part B.

¹ https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034S013b.pdf

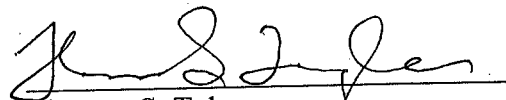
Conclusions of Law

Based on the foregoing, the undersigned concludes as a matter of law that the Optune Tumor Treatment Field Therapy services were shown to be medically reasonable and necessary and are covered under Medicare. The Beneficiary is entitled to reimbursement of all the items as billed.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

Dated: 1/15/19


Thomas S. Tyler
U.S. Administrative Law Judge

1013859



**Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Cleveland Field Office
Cleveland, Ohio**

Appeal of:	ALJ Appeal No.: 1-5956694873
Beneficiary:	Medicare Part: C
HICN: *****6690A	Before: Thomas S. Tyler U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, we find a **FAVORABLE** decision for the Appellant.

Procedural History

The Beneficiary was an enrollee of Selectcare of Texas/Universal American, a Medicare Advantage Plan (the Plan). The Beneficiary requested that the Plan grant pre-approval for tumor treatment field therapy (E0766). The Plan denied the request and the Beneficiary appealed. On February 14, 2017, Maximus Federal Services, the qualified independent contractor (QIC), issued an unfavorable decision. The QIC determined that the Plan did not have to grant pre-approval for the tumor treatment field therapy because it determined it is not a covered benefit.

An appeal and request for an Administrative Law Judge (ALJ) Hearing, pursuant to 42 C.F.R. § 405.1002(a), was timely filed and received by the Office of Medicare Hearings and Appeals (OMHA). The amount in controversy allows for an ALJ hearing.

The undersigned ALJ held a telephone hearing on April 13, 2017, at 11:00 AM ET in Cleveland, Ohio. Tonya Lane, with Novocure, Inc. (the provider) appeared on behalf of the Beneficiary. The Plan participated through Knijur Callins, Manager Appeals and Grievances, and Dr. Manasi Kekani, MD. The witnesses were sworn according to law. This case was decided pursuant to the Administrative Procedure Act (5 U.S.C. § 551 et. seq.), Title XVIII of the Social Security Act (the Act), and implementing regulations and policy. All exhibits were admitted to the record without objection and were considered in reaching this decision.

Issues

The issue before the ALJ is whether the Plan must pre-approve the Beneficiary's request for tumor treatment field therapy.

Findings of Fact

After a *de novo* review, the ALJ finds the following facts by a preponderance of the evidence:

The Beneficiary, a 71 year-old man was enrolled in TexanPlaus Classic MAPD plan (the Plan) since January 21, 2013. (Ex. 4, p. 10). The Beneficiary has been diagnosed with glioblastoma multiforme. Initially, he presented with a flashing light symptom in his left eye accompanied by blurry vision and mild confusion while golfing. Imaging revealed a contrast enhancing mass in the right temporal lobe and he underwent a craniotomy on November 15, 2016. Pathology confirmed the diagnosis. After his resection he began chemoradiation. His treating physician, Dr. _____, prescribed Optune in combination with temozolomide maintaining that it is currently the best treatment option for this type of cancer. (*Id. at p. 18*). Dr. _____

explained in a letter dated December 30, 2016 that Optune is an "innovative approach to cancer treatment, using tumor treating fields (TTFields) to interfere with the division of malignant cells. TTFields therapy is a locally or regionally delivered treatment that uses alternating electric fields to disrupt the rapid cell division exhibited by cancer cells. GBM patients treated with TTFields wear insulated transducer arrays on the scalp attached to the portable electric field generator". (*Id. at p. 19*).

Optune received pre-market approval from the FDA for recurrent glioblastoma in April 2011. In 2015, Optune received pre-market approval from the FDA for newly diagnosed glioblastoma in combination with temozolomide after standard surgical resection and radiation therapy. (*Id.*). Dr. _____ stated that he has achieved excellent outcomes in treating patients like the Beneficiary and that there are limited treatment options for this orphan disease. (*Id. at p. 20*).

Dr. _____ submitted an authorization request form for the TTFields therapy on December 5, 2016. (Ex. 2, p. 7). The Plan denied the request for pre-approval. On January 20, 2017, the Plan received a reconsideration request for the office of Dr. _____ requesting reconsideration of the Plan's decision to deny authorization of the electrical stimulation device. The Plan and QIC denied the request for authorization maintaining that the device is not a Medicare covered benefit. (Ex. 4, p. 10).

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS),

provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. (§ 1869(b)(1)(A) of the Act).

The Secretary of HHS has delegated her authority to administer the nationwide hearings and appeals system for the Medicare program to the Office of Medicare Hearings and Appeals (OMHA). (See 70 Fed. Reg. 36386, 36387 (June 23, 2005). OMHA is staffed with Administrative Law Judges who hear the third level of appeal for Medicare decisions. The Administrative Law Judges issue the final decisions of the Secretary, except for decisions appealed and reviewed by the Medicare Appeals Council. (*Id.*)

A hearing before an Administrative Law Judge is only available if the remaining amount in controversy meets the amount set forth in the regulations. (See 71 Fed. Reg. 75250 (December 14, 2006)). The request for hearing is timely if filed within sixty (60) days after receipt of a QIC reconsideration decision. (See 42 C.F.R. § 405.1014). Here those two requirements were met.

B. Scope of Review

“The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party’s favor “unless an ALJ notifies the parties an issue that was decided would be reopened prior to the hearing.” 42 C.F.R. § 405.1032(a).

C. Standard of Review

“An ALJ conducts a de novo review and issues a decision based on the entire hearing record, including the hearing testimony.” (42 C.F.R. § 405.1000(f)).

II. Principles of Law

A. Statutes and Regulations

The Medicare rules say that health plans must provide coverage for a medical service or item if regular Medicare would cover it. (42 C.F.R. § 422.101).

B. The Plan

The Plan’s Evidence of Coverage states that it covers items and services in accordance with Medicare rules. (Ex. 1, p. 42).

C. Local Coverage Determination

Local Coverage Determinations (LCDs) are developed by Medicare contractors to help determine whether certain items or services are covered. These LCDs are binding on the Medicare contractors in determining what items are covered but are not binding on ALJs. However, they are required to be given deference by an ALJ and any failure to follow an LDC must be explained.

Local Coverage Determination, L34823 addresses tumor treatment field therapy (TTFT). It states:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

For an item to be covered by Medicare, a detailed written order (DWO) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed DWO, the item will be denied as not reasonable and necessary.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

A4555 ELECTRODE/TRANSDUCER FOR USE WITH ELECTRICAL STIMULATION DEVICE USED FOR CANCER TREATMENT, REPLACEMENT ONLY

E0766 ELECTRICAL STIMULATION DEVICE USED FOR CANCER TREATMENT, INCLUDES ALL ACCESSORIES, ANY TYPE

ANALYSIS

The Appellant has requested that the Plan pre-approve tumor treatment field therapy in order to treat the Beneficiary's brain cancer. The Plan maintains that Medicare does not cover the item and therefore it is not able to cover it. Consequently, notwithstanding the Beneficiary's physician's request, the Plan has declined to grant pre-approval for the TTField therapy.

As noted in the law section above, in a Medicare Advantage Plan, the Plan is required to provide to the Beneficiary the same benefits that the Beneficiary would receive under original Medicare. (42 C.F.R. § 422.101). The Plan's Evidence of Coverage, which acts as the contract between the Beneficiary and the Plan states that basic requirement as follows; "As a Medicare health plan, TexanPlus Classic (HMO) must cover all services covered by Original Medicare and must follow Original Medicare's coverage rules." (Ex. 1, p. 42).

The Local Coverage Determination that addresses TTField therapy, L34823, specifically denies coverage. It states that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. The LCD does not provide any circumstances under which TTField therapy would be covered. The Plan maintained at hearing that it is required to follow CMS rules and

guidance in approving Medical services. (*Hearing CD*). It stated that in light of the specific denial in the applicable LCD, the Plan is unable to grant approval of the TTField therapy. (*Id.*)

The Appellant noted that the Beneficiary in this case has glioblastoma and was given a prescription by his treating physician to use both TTField therapy and temozolomide. (*Id.*) The Appellant stated that it understands that there is an LCD that states that TTField therapy is not medically reasonable and necessary but noted that the last revision of the LCD L34832 was in 2013. (*Id.*) The Appellant explained that the Optune therapy system that is at issue in this case was FDA approved for treatment of glioblastoma in conjunction with temozolomide on October 5, 2015. The Appellant also stated that although ALJ decisions are not binding on other ALJs, a dozen favorable decisions have been issued by OMHA judges. (*Id.*)

While we acknowledge that the Plan appropriately considered LCD L34832 in making the decision to deny the TTField therapy in this case based upon the unambiguous pronouncement that "tumor treatment field therapy (E0766) will be denied as not reasonable and necessary," we decline to follow that statement in the LCD. The Code of Federal Regulations identify the applicability of Local Coverage Determinations. It states that LCDs are required to be adhered to by Medicare contractors. (42 C.F.R. §405.1062). However, Administrative Law Judges and the Medicare Appeals Council are not bound by LCDs. If an ALJ declines to follow an LCD in a particular case, he or she may do so, but must explain why the policy was not followed. (*Id.*)

In this case, LCD L34832 says that TTField therapy will be denied as not reasonable and necessary but it does not provide any justification for that statement. The treatment that the Appellant is seeking is called "Optune." "Optune is a portable battery or power supply operated device which produces alternating electrical fields, called tumor treatment fields (TTFields) within the human body. The TTFields are applied to the patient's shaved head by means of electrically insulated surface transducer arrays, such that resistively coupled electric currents are not delivered to the patient. The TTFields disrupt the rapid cell division exhibited by cancer cells." https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034S013b.pdf

We conclude that the LCD at issue in this case was obviated by studies and FDA conclusions regarding the demonstrated therapeutic benefits of the Optune technology. First, we confirmed the Appellant's statement that the LCD was last updated in 2013. At that time, it is likely that TTField therapy was an emerging technology that was not fully recognized as an effective treatment of this particular brain cancer. However, at around the same time of the last LCD update, there were studies conducted and the results published passing on the efficacy of the use of TTField therapy, most notably the Optune (NovoTTF-100A therapy), for recurrent and new diagnoses of glioblastoma. *Stupp et al., NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma: a randomized phase III trial of a novel treatment modality.* Eur J Cancer. 2012 Sep; 48(14):2192-202. The results of further studies were presented just recently in the Annual Meeting of the American Association for Cancer Research. *Stupp, Hegi, Idbaih, et al. Tumor treating fields added to standard chemotherapy in newly diagnosed glioblastoma (GBM): final results of a randomized, multicenter phase III trial,* Program and Abstracts of the 2017 Annual Meeting of the American Association for Cancer Research April 1-April 5, 2017 Washington, D.C. Abstract LBA AACR CT007. The results of these studies determined that Optune in combination with temozolomide was an effective treatment of this particular brain

cancer, whether newly diagnosed or recurrent, that resulted in significant improvement in life expectancy of most patients. Moreover, Optune was approved by the FDA for use in the treatment of newly diagnosed glioblastoma on October 5, 2015¹.

We are also persuaded by the Beneficiary's medical provider. The Beneficiary's physician prescribed the treatment at issue in this case and credibly explained in a letter in the file that the treatment had excellent results for others with the Beneficiary's disease and noted that there are few other promising treatment options.

On the basis of the foregoing, we find that the above-identified study conclusions and the recent FDA approval of the efficacy of Optune in the treatment of glioblastoma that occurred since the last update of the LCD L34832 causes us to decline to follow the LCD. No explanation was provided by the LCD for the failure to cover the TTField therapy and overwhelming medical evidence indicates the treatment will be effective for the Beneficiary.

Consequently, we require the Plan to grant pre-approval for coverage of the TTField therapy requested by the Beneficiary's physician.

Conclusions of Law

The ALJ concludes that the Plan is required to grant pre-approval for tumor treatment field therapy requested by the Beneficiary's physician.

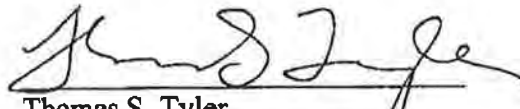
Order

The Plan is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated: _____

APR 20 2017


Thomas S. Tyler
U.S. Administrative Law Judge

¹ https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034S013b.pdf



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
 Cleveland Field Office
 Cleveland, Ohio

Appeal of: **Julie Miles with Novocure**
 REDACTED

ALJ Appeal No.: **1-8190004001**

Beneficiary: REDACTED

Medicare Part C

HICN: *****3224A

Before: **Thomas S. Tyler**
 U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, a **FAVORABLE** decision is entered for the Appellant.

Procedural History

Novocure, the provider of tumor treatment field therapy ("TTFT"), through Julie Miles, requested pre-approval for TTFT on behalf of the enrollee/beneficiary, REDACTED for treatment of his frontal anaplastic oligodendroglioma (WHO grade 2) that has become a glioblastoma. The Beneficiary is an enrollee in a Part C, Medicare Advantage Plan, Mercy Care Advantage (the "Plan") and also receives AHCCS (Medicaid) benefits. Novocure requested pre-approval for the services and for the services to be covered as in-network since they are the only provider of this device. The Plan denied the requests based upon language in LCD L34823 that states that TTFT is not medically reasonable and necessary. The Beneficiary appealed to the Qualified Independent Contractor (the QIC), MAXIMUS Federal Services.

On December 4, 2018, the QIC affirmed the previous denials and determined that the service being requested is not a covered benefit under the Plan's coverage. The Beneficiary submitted a timely request for an Administrative Law Judge (ALJ) hearing to the Office of Medicare Hearings and Appeals (OMHA). The amount in controversy meets the jurisdictional requirement for a hearing before OMHA.

A telephone hearing in this matter was held on January 22, 2019 at 11:00 AM EST/9:00 AM MST in Cleveland, Ohio before the undersigned ALJ. Ms. Debra Parrish, Esq., was obtained by the Appellant as his representative for the hearing. Julie Miles appeared on behalf of Novocure and provided testimony and argument. The Plan was represented by Aikaterine Vervilos, Esq.,

who presented argument and the testimony of Plan personnel Dr. Brent Nelson, MD and Chris Macias, Compliance Officer. All witnesses were sworn according to law.

Just in advance of the hearing, both Ms. Parrish and Ms. Miles provided documents that had previously not been supplied to the Plan and Medicare contractors before their decisions. These documents included Journal of American Medical Association articles from 2017 and 2018, a letter from HHS dated October 5, 2015 concerning a request for premarket approval of Optune (TTFT device) and a disk containing hundreds of pages which include clinical studies (some of which are already in the record), NCCN guidelines, favorable ALJ decisions, etc. The ALJ determined that the JAMA articles are not evidence but are research articles and allowed those documents into the record as research material. The ALJ determined that HHS October 5, 2015 letter regarding the request for reconsideration of use of the Optune device as well as the disk containing hundreds of pages including NCCN guidelines and prior favorable ALJ decisions would be excluded because of their late submission and failure to be provided to the Plan for review in advance of the hearing. The ALJ did note that many of the documents on the disk are also in the record or easily accessible as guidance in the public domain and could be considered despite their exclusion from the hearing record. The documents denied admission are included in the record under separate cover.

Issue

The issue is whether the Plan is required to provide approval of coverage for the electric stimulator treatments/TTFT with Novocure.

Findings of Fact

The Beneficiary in this case is a 51 year-old man who was diagnosed with oligodendroglioma and has been under the care and treatment of REDACTED M.D., at Barrow Neurology Clinic since his diagnosis. He underwent a resection of the tumor on April 19, 2006 which revealed anaplastic oligodendroglioma World Health Organization (WHO) grade II. In 2008 he started to have increased seizure activity which resulted in a subdural grid placement and a second resection of the tumor, which revealed a WHO grade III tumor. Since 2008, he has undergone Gamma Knife radiosurgery for nodular enhancement, placed on Bevacizumab, Temodar, third resection and right frontal biopsy plus interstitial thermal therapy. He also has a programmable ventriculoperitoneal shunt to drain excess fluid from the ventricle (in the brain) via a tube into his abdomen. A programmable shunt has an adjustable valve which prevents the fluid from moving in the wrong direction and only lets fluid drain when the pressure is too high.¹ In 2018, the Beneficiary's cancer had characteristics that enabled it to be diagnosed as a glioblastoma (GBM). The updated WHO guidelines recommend classifying this type of cancer with that designation. His physician prescribed the Optune system (E0766) due to the aggressive nature and extremely limited treatment options for this condition. The physician felt this was the best option for treating his anaplastic oligodendroglioma (i.e. glioblastoma multiforme). (*Exhibit 4, p. 19-20; Hearing CD*).

¹ This information can be found at: <https://www.urmc.rochester.edu/neurosurgery/for-patients/treatments/programmable-shunt.aspx>

The physician argued that the device has been approved by the FDA for patients with glioblastoma multiforme tumors that recur after maximal surgical and radiation treatments. In addition, he noted that it has been covered by Aetna, Cigna, Anthem BlueCross and BlueShield along with several others. Lastly, he argued that this device has been employed successfully for patients such as the Beneficiary. (*Exhibit 4, p. 20*).

Optune, previously known as the NovoTTF-100A System, is durable medical equipment that delivers alternating electric fields or tumor treating fields to the brain. Optune is intended as a treatment for adult patients with histologically-confirmed glioblastoma (GB). The device consists of an electric field generator which is connected to four insulated transducer arrays. The arrays are placed on the patients scalp and deliver the tumor treating fields therapy (TTFT) to the patient's glioblastoma.

The Beneficiary had the device implanted on October 12, 2018 by REDACTED M.D., at Barrow Neurology Clinic. (*Exhibit 2, pgs. 5-10*).

The record contains multiple articles regarding treatment of glioblastoma. (*Exhibit 1, pgs. 264-454*).

Ms. Miles argued at hearing that Optune is included in the National Comprehensive Cancer Network guidelines for recurrent glioblastoma and for newly diagnosed glioblastoma and that it is a Food and Drug Administration approved drug for treatment of this cancer. (*Hearing Testimony*).

The Plan argued that they are only required to cover what regular Medicare covers and Medicare does not provide coverage for the item at issue pursuant to the relevant Local Coverage Determination, L34823. (*Id.*).

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) § 1869(b)(1)(A).

In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *Id.*

A hearing before an ALJ is only available if the remaining amount in controversy is \$160 or more. *See* 76 Fed. Reg. 59138 (Sept. 23, 2011) and 42 C.F.R. §405.1006(b)(2). The request for

hearing is timely if filed within sixty days from the date the party receives notice of the QIC's reconsideration. *See* 42 C.F.R. § 405.1014(b)(1).

B. Scope of Review

The issues before the administrative law judge include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the party's favor. However, if evidence presented before the hearing causes the administrative law judge to question a favorable portion of the determination, the administrative law judge will notify the parties before the hearing and may consider it an issue at the hearing. 42 C.F.R. § 405.1032(a).

C. Standard of Review

ALJs from the Office of Medicare Hearings and Appeals ("OMHA") conduct "de novo" hearings. That means, the ALJs are not bound by any prior determinations and can make a decision on the basis of the entire record, including the evidence presented through testimony at hearing.

II. Principles of Law

A. Medicare Advantage Plan

Under the Social Security Act, the Medicare Advantage (MA) program allows private health insurance companies to provide individuals with Medicare coverage. A Medicare Advantage Plan must provide the services currently available under Medicare Parts A and B, and may provide additional services if specified in its policy. 42 C.F.R. § 422.100(a). Health plans must pay for a medical service or item if regular Medicare would pay for it. 42 C.F.R. § 422.101. However, MA organizations may specify the networks of providers from whom enrollees may obtain services as long as the MA organization ensures that all covered services, including additional or supplemental services contracted for (or on behalf of) the Medicare enrollee, are available and accessible under the plan with reasonable promptness and in a manner which assures continuity in the provision of benefits. §1852 (d) of the Social Security Act; 42 U.S.C § 1395w-22(d); 42 C.F.R. § 422.112.

B. National and Local Coverage Determinations

Administrative Law Judges may also give consideration to the manuals and rulings issued by the CMS in determining benefit coverage and eligibility. Although not binding on the Administrative Law Judge, the respective manuals provide guidance in the administration of the Medicare program. (*Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87 (1995)).

Section 1871(a)(2) of the Act provides that no rule, requirement or statement of policy, other than a National Coverage Determination ("NCD"), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program unless it is promulgated as a regulation by CMS. However, although not subject to the force and effect of the law, CMS and its contractors, have issued policy and guidelines, including Local

Coverage Determinations (LCD's) that describe criteria for coverage for selected types of medical services and supplies. NCDs promulgated by the Secretary of HHS under the authority of § 1862(a)(1) of the Act dictate the criteria under which specified services, procedures or supplies are covered by Medicare. NCDs are binding upon ALJs. 42 CFR §405.732(a)(4). "An ALJ may not disregard, set aside or otherwise review an NCD." (42 CFR §405.732(b)(1)). LCDs are binding upon Medicare Advantage Plans and Medicare contractors when reviewing claims for coverage. However, ALJs, attorney adjudicators and the Medicare Appeals Council "are not bound by LCDs...but will give substantial deference to these policies if they are applicable to a particular case." (42 C.F.R. §405.1062(a)). In the event that an ALJ declines to follow an LCD, he or she must explain the reasons why the policy was not followed. (Id. at §405.1062(b)).

There is no NCD specific to tumor treatment field therapy. However, there is a local coverage determination that can be found at L34823. It provides in part that tumor treatment field therapy will be denied as not reasonable and necessary. However, policy article A52711 provides that tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Code E0766 is in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories. Separate billing of supplies and/or accessories will be denied as unbundling.

C. Mercy Care Health Plan Evidence of Coverage

As noted in the statement of facts, the Plan and the Beneficiary entered into a Medicare Plan that provides physician services and coverage for specialists. The Plan's EOC describes the services that are covered and the cost to the enrollee for the services being provided. The EOC also informed the Beneficiary that the Plan must cover all services covered by Original Medicare and other services and must follow Original Medicare's coverage rules for these services. It also informed the Beneficiary what services would be covered and how to find in-network providers. (Exhibit 1, pgs. 44-45).

The Plan provides coverage for durable medical equipment ("DME") and related supplies that are medically necessary and covered by Original Medicare. Some covered items were identified as wheelchairs, crutches, powered mattress, diabetic supplies, IV infusion pumps and speech generating devices just to name a few. (*Id.*, at pg. 71).

D. Optune System – Novocure²

Novocure is an oncology company developing a profoundly different cancer treatment utilizing a proprietary therapy called Tumor Treating Fields, the use of electric fields tuned to specific frequencies to disrupt solid tumor cancer cell division. Novocure's commercialized product is approved for the treatment of adult patients with glioblastoma. Novocure has completed clinical trials investigating Tumor Treating Fields in brain metastases, non-small cell lung cancer, pancreatic cancer, ovarian cancer, liver cancer and mesothelioma.

Optune's approved indications are intended as a treatment for adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme (GBM). Optune with temozolomide is indicated for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy.

For the treatment of recurrent GBM, Optune is indicated following histologically-or radiologically-confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted.

Optune is contraindicated if the patient has an active implanted medical device, a skull defect (such as, missing bone with no replacement), or bullet fragments. Use of Optune together with implanted electronic devices has not been tested and may theoretically lead to malfunctioning of the implanted device. Use of Optune together with skull defects or bullet fragments has not been tested and may possibly lead to tissue damage or render Optune ineffective.

In a news release dated December 3, 2015, Novocure discussed programmable versus non-programmable shunts and adverse reports.³ It stated, in pertinent part, the following: "Adverse events reported by the 49 patients with implanted medical devices did not raise any new safety concerns regarding the use of TTFields therapy, and the analysis indicates that TTFields therapy is safe in patients with non-programmable shunts. Further investigation is needed to conclude whether TTFields therapy is safe in patients with programmable shunts and in patients with pacemakers/defibrillators." At hearing, the Novocure representative stated that TTFields Therapy does not interact with shunts of the type that the Beneficiary has but that there is further investigation concerning the potential interaction of Optune with patients using pacemakers and defibrillators. (*Hearing CD*).

Analysis

The Provider requested that the Medicare Advantage Plan provide coverage for the TTFT from an out-of-network provider and that the service be covered as in-network on the claim that (1) this

² This information can be found at: <https://www.novocure.com/novocure-announces-that-the-medicare-dme-macs-have-accepted-the-local-coverage-determination-reconsideration-request-for-optune/>

³ This information can be found at: <https://www.novocure.com/retrospective-analysis-shows-optune-safe-in-glioblastoma-patients-with-implanted-non-programmable-shunts-2/>

DME item is medically reasonable and necessary (2) this is the best and potentially only treatment option for the Beneficiary at this point and (3) Novocure is the only provider of the this item. The item/service has been denied because the Plan and Medicare contractor have concluded that the applicable LCD prohibits coverage of this item. At issue in this case is whether approval/reimbursement can be made for the TTFT therapy provided to the Beneficiary on October 15, 2018.

As stated earlier, there is no NCD that addresses tumor treatment field therapy. Therefore, we look to the current local coverage determination for guidance. In this case, the LCD L34823 does deal with code E0766, tumor treatment field therapy. It states that tumor treatment field therapy will be denied as not reasonable and necessary.

As noted in the law section above, in a Medicare Advantage Plan, the Plan is required to provide to the Beneficiary the same benefits that the Beneficiary would receive under original Medicare. (42 C.F.R. § 422.101). The Plan's Evidence of Coverage, which acts as the contract between the Beneficiary and the Plan states that basic requirement. (Ex. 1, p. 44-45). Local Coverage Determinations provide guidance for determining Medicare coverage of medical items and services so Plans and Medicare contractors utilize those documents in determining coverage issues.

As noted above, the Local Coverage Determination that addresses TTField therapy, L34823, specifically denies coverage. It states that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. The Plan maintained at hearing that it is required to follow CMS rules and guidance in approving Medical services. (*Hearing CD*). It stated that in light of the specific denial in the applicable LCD, the Plan is unable to grant approval of the TTField therapy. (*Id.*). The Plan stated that no other basis was used for denying coverage other than the statement in the LCD. (*Id.*).

The Appellant noted that the Beneficiary in this case has been diagnosed with glioblastoma and was given a prescription by his treating physician to use both TTField therapy and temozolomide. (*Id.*). The Beneficiary's representative stated that she understands that there is an LCD that states that TTField therapy is not medically reasonable and necessary but noted that the last revision of the LCD L34832 was issued prior to phase III studies being concluded regarding its medical benefit. (*Id.*). The Appellant explained that the Optune therapy system that is at issue in this case was FDA approved for treatment of glioblastoma in conjunction with temozolomide on October 5, 2015. The Appellant also stated that although ALJ decisions are not binding on other ALJs, numerous favorable decisions have been issued by OMHA judges. (*Id.*).

LCD L34832 does specifically state that TTField therapy will be denied as not reasonable and necessary. The tumor treatment field therapy that the Appellant is seeking is called "Optune." "Optune is a portable battery or power supply operated device which produces alternating electrical fields, called tumor treatment fields (TTFields) within the human body. The TTFields are applied to the patient's shaved head by means of electrically insulated surface transducer arrays, such that resistively coupled electric currents are not delivered to the patient. The TTFields disrupt the rapid cell division exhibited by cancer cells." https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034S013b.pdf. While we acknowledge

that the Plan and QIC appropriately considered LCD L34823 in making the decision to deny the Optune treatment in this case based upon the unambiguous pronouncement that the type of treatment is not reasonable and necessary, we decline to follow that statement in the LCD. No explanation was provided by the LCD for the failure to cover the TTField therapy. Certainly, the LCD is not required to include reasons for the denial of non-covered services. However, in giving an LCD its required deference when considering whether to abide by a pronouncement that is not binding on an ALJ, the reason for the non-coverage would be helpful to assess the applicability of the LCD. Here, we cannot determine the reasons for non-coverage but find that the rationales for coverage are extensive. In exercising our review authority, the Code of Federal Regulations identifies the applicability of Local Coverage Determinations. Administrative Law Judges and the Medicare Appeals Council are not bound by LCDs. If an ALJ declines to follow an LCD in a particular case, he or she may do so, but must explain why the policy was not followed. (42 C.F.R. §405.1062(a)).

Without an explanation in the LCD as to why TTF therapy is considered as not medically reasonable and necessary, we are left to speculate. The TTFT was likely an emerging technology that had not been widely reviewed or tested for medical efficacy at the time the language was included in the LCD limiting its coverage. However, Optune was approved by the FDA for use in the treatment of newly diagnosed glioblastoma on October 5, 2015⁴. Moreover, at around the same time of the last LCD update, there were studies conducted and the results published passing on the efficacy of the use of TTField therapy, most notably the Optune (NovoTTF-100A therapy), for recurrent and new diagnoses of glioblastoma. *Stupp et al., NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma: a randomized phase III trial of a novel treatment modality*. Eur J Cancer. 2012 Sep; 48(14):2192-202. The results of further studies were presented in the Annual Meeting of the American Association for Cancer Research. *Stupp, Hegi, Idaihi, et al. Tumor treating fields added to standard chemotherapy in newly diagnosed glioblastoma (GBM): final results of a randomized, multicenter phase III trial*, Program and Abstracts of the 2017 Annual Meeting of the American Association for Cancer Research April 1-April 5, 2017 Washington, D.C. Abstract LBA AACR CT007. The results of these studies determined that Optune in combination with temozolomide was an effective treatment of this particular brain cancer, whether newly diagnosed or recurrent, that resulted in significant improvement in life expectancy of most patients.

We are also persuaded by the statement of the Beneficiary's medical provider. The Beneficiary's physician prescribed the treatment at issue in this case and mentioned the FDA approval of the Optune device and the studies supporting its use. He credibly explained that the treatment had excellent results for others with the Beneficiary's disease and noted that there are few other treatment options following the resection and radiation. (Exhibit 4, pp. 19-20).

On the basis of the foregoing, we decline to follow the LCD. The FDA approval of Optune, the overwhelming medical research evidence and the written statement by the Beneficiary's physician discloses that Optune is effective in extending the lives of patients who have been newly diagnosed or have recurrent glioblastoma. We do not fault the Plan or Medicare contractors for coming to a different conclusion. They adhered to the pronouncement in the

⁴ https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034S013b.pdf

LCD. However, if ever there was a reason for an ALJ to vary from the strict, unexplained pronouncement in an LCD, it is this case where the very life of the Beneficiary holds in the balance, with very few, if any, other medical options to treat him and prolong his life aside from the treatment provided by the Optune device. Consequently, we require the Plan to grant approval for coverage of the TTField therapy requested by the Beneficiary's physician.

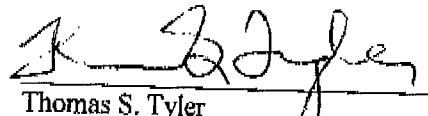
Conclusions of Law

The ALJ concludes that the Plan is required to grant approval for tumor treatment field therapy requested by the Beneficiary's physician.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

Dated: 1/24/19


Thomas S. Tyler
U.S. Administrative Law Judge



**Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City, MO**

Appeal of:	NOVOCURE, INC	ALJ Appeal No.:	1-2528031684
Beneficiary:		Medicare:	Part B
DOS:	JUNE 9, 2013, JULY 9, 2013 AUGUST 9, 2013		
HICN:	*****3072A	Before:	Angela Wilt Administrative Law Judge

DECISION

After carefully considering the evidence in the record and arguments presented at hearing, a **FULLY FAVORABLE** decision is entered for the appellant. The claim for the durable medical equipment provided to the beneficiary on the dates of service at issue are covered are covered under Part B of Title XVIII of the Social Security Act.

PROCEDURAL HISTORY

This appeal follows prior adverse decisions of the Administrative Contractor and the Qualified Independent Contractor, both of which denied the appellant's claim for durable medical equipment provided to the beneficiary. The appellant then filed a request for an administrative law judge (ALJ) hearing.

The Office of Medicare Hearings and Appeals ("OMHA") received appellant's timely request for an ALJ hearing. 42 C.F.R. § 405.1014(b)(1). The amount in controversy meets the jurisdictional requirements for an ALJ hearing. Accordingly, appellant's claim satisfies all the jurisdictional requirements for an ALJ hearing before OMHA. 42 C.F.R. §§ 405.1002(a) & 405.1006(b)(1).

Hearing on this matter was held on at August 28, 2017, which Stephany Hales, Esq., and Justin Kelly, Senior Director of Health Policy, appeared representing the appellant. Exhibits 1-4 were admitted into evidence without objection.¹ Upon conclusion of argument and testimony, the record was closed and the hearing was concluded.

¹ Exhibit 3 included medical records that were admitted upon a finding of good cause as the lower levels of review had the records based upon their decisions, but the records were not included in the administrative law judge file.

ISSUES

The issues before the ALJ include all of the issues brought out in the initial determination, coverage determination, or organization determination; redetermination; or reconsideration that were not decided entirely in a party's favor, for the claims or other appealed matters specified in the request for hearing.

FINDINGS OF FACT

A preponderance of the evidence in the record establishes the following facts:

1. The beneficiary, a female, was diagnosed with left frontal glioblastoma multiforme, (GBM), which caused difficulty finding words, speech hesitancy and paraphasic errors. (Exh. 2, p. 1-49, 166-244). On April 27, 2012, she underwent a craniotomy, followed by radiation and chemotherapy from May 21, 2012 through July 2, 2012. (Exh. 3, p. 156). The beneficiary's medical records recorded that during her various therapies, her symptoms worsened and an MRI revealed progression of the cancer to include the right frontal lobe. *Id.* She received intravenous medication of Avastin, underwent additional radiation, and her oral chemotherapy was switched. *Id.* However, her physicians noted that in addition to the progressive growth of the cancer, she also developed pancytopenia, and her chemotherapy had to be held. (Exh. 2, p. 179).
2. The beneficiary's physician then suggested that the beneficiary consider trying the NovoCure Device NovoTTF-100A System, which furnishes tumor treatment therapy with minimal side effects. (Exh. 2, pp. 239-240). The beneficiary began using the device in October 2012, with excellent tolerance. (Exh. 2, p. 244). The device was billed under E1399. (Exh. 1, p. 2).
3. During the dates of service at issue, the medical records recorded that the beneficiary received and used the NovoTTF-100A System for June, July and August 2013, and she reported no side effects with the device. (Exh. 3, pp. 102-139).
4. The appellant submitted a copy of the April 8, 2011, letter from the Food and Drug Administration providing approval for the premarket approval application for the Novo TTF-100A System in 2001. (Exh. 3, pp. 163-169). The device, which furnishes TTF therapy, is indicated for treatment of adult patients with histologically-confirmed GBM, following histologically or radiologically-confirmed recurrences in the supra-tentorial region of the brain after receiving chemotherapy. *Id.* It is intended to be used as a monotherapy and an alternative to standard medical therapy for glioblastoma after surgical and radiation options have been exhausted. (Exh. 3, p. 163).
5. The submitted studies show that the Novo TTF-100A System is a portable wearable cap-like device that delivers alternative electric fields to the brain to disrupt the formation of the mitotic spindle in the dividing cancer cell. This is similar to the taxing chemotherapy that leads to the cancer cell death. The therapy is specific to GBM cells. (Exh. 2, pp. 49-162). GBM is an aggressive, primary brain cancer. Initially, patients had a life expectancy of twelve to fifteen months. If the disease recurs, about twenty percent of the

patients are eligible for surgery, and most are not eligible for additional radiation as they have maxed out their radiation dose on the initial radiation therapy. The prior chemotherapy is not an option when a reoccurrence occurs. Therefore, the Novo TTF-100A System becomes an option for the GBM patients with very limited options. *Id.*

6. The appellant also submitted two letters from the beneficiary's provider, one dated July 11, 2013, and the other dated November 15, 2013, that discussed the medical necessity of the Novo TTF-100A System; that there are limited treatment options for individuals suffering from glioblastoma (GBM), and that the beneficiary had exhausted all other FDA-approved treatments that could have been benefited her; and the Novo TTF-100A System was the most promising treatment option for her at that time. (Exh. 3, pp. 22-30). The November 15, 2013 letter provided information on the randomized 28-center phase III clinical trial conducted on the NovoTTF-100A System and the conclusion was that the Novo TTF-100A system appears comparable to chemotherapy regimens commonly used in glioblastoma and the toxicity and quality of life favored the TTF therapy. (Exh. 3, p. 26).²
7. Prior to the dates of service at issue, CMS advised that the NovoTTF-100A System fell within the DME benefit category. (Exh. 1, p. 65).
8. Finally, the appellant testified that there was in fact evidence regarding the suggested manufacturer's retail price provided by the appellant. The appellant advised that the suggested price is reflected in the price stated in the submitted claims filed with the various review levels. (Hearing testimony).

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. 42 C.F.R. § 405.1014; Social Security Act ("the Act") section 1869(b)(1)(A). The Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary unless later reviewed by the Medicare Appeals Council. *Id.*

To be timely, the request for hearing must be received by OMHA within sixty days after the Appellant receives the QIC's reconsideration decision. The Appellant is presumed to have received the QIC's reconsideration five days after the date noted on the first page of the reconsideration, unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3).

² See also <http://dx.doi.org/10.1016/j.ejca.2012.04.011>

To be entitled to a hearing before an ALJ, a party must meet the amount in controversy requirements. 42 C.F.R. § 405.1002(a)(2).

B. Scope of Review

The ALJ considers all issues not decided entirely in the Appellant's favor at any prior level of review. 42 C.F.R. § 405.1032. The ALJ may give notice to the parties if any other issue will be addressed at the hearing. *Id.* The ALJ may also decide a case on the record and not conduct a hearing if the appellant and all other parties indicate in writing they do not wish to appear at a hearing. 42 C.F.R. §§ 405.1000(g), .1032(a) and .1038. The ALJ may also decide a case on the record if the evidence in the hearing record supports a wholly favorable finding. *Id.*

A party may not offer new evidence for the first time at the ALJ level unless the ALJ finds good cause exists why the evidence was not submitted to a prior decision maker. This restriction on new evidence is not applicable to unrepresented beneficiaries or to oral testimony given during the course of a hearing. 42 C.F.R. §§ 405.966(c), 405.1018(c-d), 405.1028(a), and 405.1030(c).

C. Standard of Review

The ALJ reviews and evaluates the evidence without regard to the findings made by the lower levels on the claim (*de novo* review). 42 C.F.R. § 405.1000(d). The Appellant bears the burden of proving each element of the Medicare claim by a preponderance of the evidence. Sections 1814(a)(1), 1815(b), and 1833(e) of the Act; 42 C.F.R. §§ 424.5(a)(6), 405.1018, 405.1028, and 405.1030.

II. Principles of Law

A. Statutes and Regulations

The statutory authority for the Medicare program is found in Title XVIII of the Act. 42 U.S.C. § 1395 *et. seq.* One function of the Centers for Medicare and Medicare Services ("CMS"), an agency within HHS, is to administer the Medicare program. The Secretary of HHS has the authority under § 1842 of the Act to enter into contracts to provide for the administration of benefits under Part B. 42 U.S.C. § 1395(u).

The Supplementary Medical Insurance program (Part B of Title XVIII of the Act) provides coverage for a variety of medical services and supplies furnished by physicians, or by others, in connection with physicians' services, for outpatient hospital services, and for a number of other specific health-related items and services. § 1832 of the Act; *see also* 42 C.F.R. § 410.10. Notwithstanding any other provision of Title XVIII, § 1862(a)(1) of the Act states that "no payment may be made under part A or part B for any expenses incurred for items or services which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Moreover, the Secretary of HHS has authority to promulgate regulations which define or clarify the provisions of the Act. Those regulations are generally found at 42 C.F.R. § 410.1 through § 410.175. Further, under § 1833(e) of the Act, the provider is responsible for providing sufficient documentation to support that payment is due and the services were medically necessary and provided as billed. *See also* 42 C.F.R. § 424.5(a)(6).

In the event the services are found to be “not medically reasonable and necessary,” or “custodial in nature,” under § 1862(a)(1) or (9) of the Act, § 1879 of the Act provides for limitation on liability for Medicare payments. If it is determined that Medicare cannot pay for the services at issue, § 1879 may assign liability for the payment of these services. If the beneficiary had no knowledge that the services would not be covered, but the provider of the services did, then the provider is liable and cannot seek or retain payment by the beneficiary. The regulations at 42 C.F.R. § 411.400 *et seq.* and Health Care Financing Administration (“HCFA”) Ruling 95-1 address how to determine if the beneficiary or provider/supplier had the requisite degree of knowledge to make them liable under § 1879 of the Act. In general, the existence of a notice, manual, or community medical standard is sufficient to constitute notice as applicable to the provider. 42 C.F.R. § 411.406.

B. Policy and Guidance

Unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than a National Coverage Determination (“NCD”), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. § 1871(a)(2) of the Act and 42 C.F.R. § 405.860. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance describing criteria for coverage of selected types of medical items and services in the form of manuals or local coverage determinations (“LCDs”). The applicable provisions in the LCDs and Medicare manuals, although not binding on ALJs, are valid interpretive rules that are instructive and influential, and provide useful guidance in the administration of the Medicare program. *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87 (1995). Accordingly, the applicable provisions in the LCDs and Medicare manuals are entitled to substantial deference to the extent they are consistent with the Act, regulations, and rulings; deviation from them must be explained. 42 C.F.R. § 405.1062.

Medical records must be authenticated by the author. CMS, *Medicare Program Integrity Manual (MPIM) (Internet-Only Manual Publ'n 100-08)* ch. 3, § 3.3.2.4. Specifically, Medicare requires that services provided/ordered be authenticated by the author. The method used shall be a handwritten or electronic signature. Stamped signatures are not acceptable.

Medicare Benefit Policy Manual (MBPM) (Internet-Only Manual Publ'n 100-02) chapter 15, section 110, and section 110.1, provides guidance on what qualifies for durable medical equipment, when it is covered, and its definition, and states:

Expenses incurred by a beneficiary for the rental or purchases of durable medical equipment (DME) are reimbursable if the following three requirements are met:

- The equipment meets the definition of DME (§110.1);
- The equipment is necessary and reasonable for the treatment of the patient's illness or injury or to improve the functioning of his or her malformed body member (§110.1); and
- The equipment is used in the patient's home.

Durable medical equipment is equipment which:

- can withstand repeated use;

- is primarily and customarily used to serve a medical purpose;
- generally is not useful to a person in the absence of an illness or injury; and
- is appropriate for use in the home.

MBPM (Internet-Only Manual Publ'n 100-02) ch. 15, § 110, and 110.1.

All requirements of the definition must be met before an item can be considered to be durable medical equipment.

ANALYSIS

The appellant appeals the QIC's denial of coverage of appellant's claim for durable medical equipment provided to the beneficiary on June 9, 2013, July 9, 2013, and August 9, 2013. The QIC denied the claim for medical services because the medical documentation did not support the need for the device, including why this particular beneficiary should be considered for the device, and there was no documentation submitted to show the manufacturer retail price for the service billed. There is no applicable LCD for this matter.

The medical records documented that the beneficiary in this case had recurrent glioblastoma multiforme cancer, confirmed by an MRI, after previously undergoing surgery, chemotherapy and radiation. She was not a candidate for further surgery or radiation, and she had developed complications as a result of the chemotherapy, specifically, pancytopenia. Her chemotherapy had to be held. She had limited to no further options available for her recurrent GMB cancer, and her doctors suggested the NovoCure Device NovoTTF-100A System for its therapeutic help and minimal side effects. She began using the system in October 2012, and did not suffer complications or side effects. Her medical records reflect that she continued to use the NovoCure Device NovoTTF-100A System through the dates of service at issue. The beneficiary was an appropriate candidate for the use of the NovoTTF-100A System, and in fact used the device at issue.

The next issue is whether the device is a DME. Medicare defines a DME as an item that can withstand repeated use; is primarily and customarily used to serve a medical purpose; generally is not useful to a person in the absence of an illness or injury; and is appropriate for use in the home. The record adequately demonstrates that the NovoCure Device NovoTTF-100A System can withstand repeated use, is primarily used for a medical purpose, would not be useful to a beneficiary in the absence of an illness or injury, and is appropriate for use in a beneficiary's home. Therefore the NovoCure Device NovoTTF-100A System is an item of durable medical equipment.

Medicare will cover a DME if it (1) meets the definition of a DME; (2) is medically "reasonable and necessary" and (3) the equipment is used in the beneficiary's home. *MBPM (Internet-Only Manual Publ'n 100-02)* ch. 15, § 110.

The record in this case also established that prior to the dates of service at issue, the FDA had approved the manufacturer's premarket approval application for the NovoTTF-100A System in 2011. The device, according to the documentation, is indicated for the treatment of adult patients

with histologically-confirmed GBM, following histologically-or radiologically-confirmed recurrence in the brain after receiving chemotherapy.

Under the Medicare regulations, the fact that a device may be deemed non-experimental or non-investigational by virtue of its FDA classification means, as a threshold matter, only that it is eligible to be considered for Medicare coverages. 42 C.F.R. §405.201(a) (2). The appellant also offered information that numerous large and small health care insurance providers are covering this treatment for recurrent glioblastoma. (Exh. 3, p. 24). The evidence presented in the medical records and through testimony established that during the dates of services at issue, the NovoTTF-100A System had gained general acceptance within the medical community in the treatment of recurrent GBM and thus, meet the medical necessity standard for Medicare coverage. Also, CMS advised that the NovoTTF-100A System fell within the DME benefit category. (Exh. 1, p. 65).

The record supports that the NovoCure Device NovoTTF-100A System was not an experimental and/or investigational system. Two letters of medical necessity of the Novo TTF-100A System were submitted. The first letter discussed that there are limited treatment options for individuals suffering from glioblastoma (GBM), and that the beneficiary had exhausted all other FDA-approved treatments that could have been benefited her; and the Novo TTF-100A System was the most promising treatment option for her at that time. The November 15, 2013 letter discussed the numerous random phase III clinical trials on the NovoTTF-100A System, and that the conclusion was that the Novo TTF-100A system was an effective mode of cancer treatment, especially concerning the toxicity and quality of life issues. For this beneficiary, the medical records establish that the beneficiary's physician opined that the NovoCure Device NovoTTF-100A System was the only treatment available for the beneficiary.

The medical records documented that the beneficiary had undergone surgery and radiation after her initial diagnosis, and then received chemotherapy. During this period, her symptoms increased and an MRI confirmed progression of the cancer to her right frontal lobe. The beneficiary developed then pancytopenia, and her chemotherapy had to be held. The beneficiary had no further treatment options available; she was not a candidate for further surgery or radiation. At the time she began the NovoCure Device NovoTTF-100A System, it was approved by the FDA for her specific situation. According to the medical records submitted, the NovoCure Device NovoTTF-100A System was durable medical equipment, and was medically reasonable and necessary for this beneficiary.

The last issue deals with the suggested manufacturer retail price for the services billed. The documentation submitted shows that the claims were submitted with the suggested price for each claim at issue in this appeal. Therefore, sufficient documentation was in fact submitted to establish the suggested retail price.

When taken as a whole, the record establishes by a preponderance of the evidence that the durable medical equipment at issue was medically necessary and reasonable for the beneficiary for the dates of services at issue, and therefore is covered by Medicare.

CONCLUSIONS OF LAW

The decision is **FULLY FAVORABLE**. The claim for durable medical equipment medical services provided to the beneficiary on June 9, 2013, July 9, 2013, and August 9, 2013, is medically reasonable and necessary and is covered under Part B of Title XVIII of the Social Security Act.

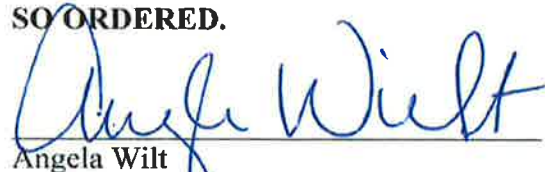
ORDER

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this Decision.

SO ORDERED.

NOV 17 2017

Dated: _____



Angela Wilt
Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Irvine, CA

Appeal of:	ALJ Appeal No.: 1-7832401008
Beneficiary:	Medicare: Part B
HICN:	Before: Mark Win Administrative Law Judge

DECISION

After careful consideration of the evidence and arguments presented in the record and at the hearing, a **FULLY FAVORABLE** decision is entered in the matter of (Appellant/Beneficiary).

PROCEDURAL HISTORY

A claim was submitted for Novacure's Optune (formerly Novacure's TTF 100-A) (Tumor Treatment Field Therapy (TTFT)), an electrical stimulation device cancer treatment (HCPCS code E0766), for dates of service of August 9, 2017, September 9, 2017, and October 9, 2017.

These services were denied by CGS Administrators, the Medicare Administrative Contractor (CGS), initially and on redetermination. On July 20, 2018, C2C Innovative Solutions, Inc., a Medicare Qualified Independent Contractor (QIC), denied the claim on reconsideration. Exh. 1, p. 1. The Appellant made a request for an Administrative Law Judge (ALJ) hearing before the Office of Medicare Hearings and Appeals (OMHA). 42 C.F.R. §405.1014(b)(1). The amount in controversy satisfies the jurisdictional requirement for a hearing pursuant to §1869(b)(1)(E) of Title XVIII of the Social Security Act (Act).

On October 23, 2018, a telephonic hearing was conducted on this matter at the OMHA Irvine Field Office in Irvine, California. The Appellant/Beneficiary (Appellant) appeared by his attorney, Bridget Noonan with Parrish Law Offices. Additionally, Dan McCoy, Manager of Case Management with Novocure, appeared on behalf of the Appellant. Hearing Recording. All exhibits were admitted into the evidentiary record without objection¹.

¹ The ALJ held the record open until October 30, 2018 to accept a post-hearing submission by the Appellant of supplemental medical records and documentation of an April 2008 trial of NovoTTF-100A together with Temozolomide compared with Temozolomide alone in patients with newly diagnosed GBM. These documents are marked Exhibit 5 and are admitted into the evidentiary record.

ISSUE

The issue on appeal is whether the Appellant is entitled to Medicare coverage for the TTFT (HCPCS code E0766) for dates of service of August 9, 2017, September 9, 2017, and October 9, 2017, under Medicare Part B, and, if not, who is responsible for the non-covered charges?

FINDINGS OF FACT

The Appellant, a 29-year-old male, was diagnosed with glioblastoma multiforme (GBM)² and underwent a gross total resection of a right-sided parietal lobe GBM on February 6, 2015. Exh. 2, pp. 26-29. He went on to receive adjuvant radiotherapy and low-dose temodar (temozolomide) between March 9, 2015 and April 24, 2015, with only one seizure episode which resolved with optimization of his anti-seizure medications. *Id.* An MRI on September 4, 2015 revealed stable postoperative and post radiation changes without evidence of any new lesions and an MRI on February 27, 2016 confirmed stability radiographically. *Id.* at 26. He has been continued on high dose adjuvant temodar therapy, which he has been tolerating well; has had slowly progressing but tolerable leg weakness; and on April 27, 2016, he saw MD, the medical oncologist supervising the high dose temodar therapy, regarding initiation of the FDA approved TTFT. *Id.* Dr. recommendation and plan of care was: 1. continue maintenance temodar, surveillance MRIs and routine evaluations clinically with the neuro-oncology team; 2. initiate tumor treating fields based on FDA approval and high-level evidence from EF - 14 and robustness analysis noting the evidence-based benefit of improving mean overall survival as well as progression-free survival of GBM when used as first-line therapy at the time of adjuvant high dose monthly temodar and thereafter (this includes ordering another MRI to be scheduled in June 2016, but the plan is to initiate tumor treating electric fields in the form of Optune prior to that scan if able, basing the treatment array planning off of the most recent available MRI from this year); and 3. continue follow-up with all multiple disciplinary neuro-oncology team and primary care team, as well. *Id.* at 26, 28. Dr. ordered the Novacure Optune TTFT. *Id.* at 7.

On October 3, 2017, a radiation oncologist noted that the Appellant had continued the additional adjuvant treatment with Optune until the present time and tolerated it well without significant side effects and without disease progression and it was recommended that he remain on continued Optune therapy and continued surveillance with MRI imaging. Exh. 3, pp. 39-40.

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services ("HHS"), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. 42 C.F.R. § 405.1014 and the Act, Title VXIII, § 1869(b)(1)(A).

² Glioblastoma is the most devastating primary malignancy of the central nervous system in adults. Most patients die within 1 to 2 years of diagnosis.
OMHA-152 (rev. 10/07)

In implementing this statutory directive, the Secretary's authority to administer the nationwide hearings and appeals system for the Medicare program was delegated to the Office of Medicare Hearings and Appeals ("OMHA"). 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, unless those decisions are later reviewed by the Medicare Appeals Council ("MAC"). *Id.*

For requests filed in calendar year 2015, the minimum amount remaining in controversy required for an ALJ hearing is \$150.00 (following application of any co-insurance or deductible).

To be considered timely, the request for hearing must be received by OMHA within sixty days after the Appellant receives the QIC's reconsideration decision. The Appellant is presumed to have received the QIC's reconsideration five days after the date noted on the first page of the reconsideration, unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3).

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in the Appellant's favor. However, if evidence presented before or during the hearing causes the ALJ to question a fully favorable decision he or she will notify the Appellant and will consider it an issue at the hearing. 42 C.F.R. § 405.1032(a).

The ALJ may decide a case on the record and not conduct an oral hearing if the Appellant and all the parties indicate in writing that they do not wish to appear before the ALJ at an oral hearing or if an examination of the record supports a finding in favor of the Appellant on every issue. 42 C.F.R. § 405.1038.

C. Standard of Review

The ALJ conducts a de novo review of each claim at issue. The Administrative Procedure Act, § 557 and 70 Fed. Reg. 36386 (June 23, 2005).

A de novo review requires the ALJ to review and evaluate the evidence without regard to the findings in the prior determinations on the claim and make an independent assessment in reliance upon the evidence and controlling laws. The burden of proving each element of a Medicare claim lies with the Appellant and is by preponderance of the evidence (i.e. satisfied through the submission of sufficient documentary evidence in accordance with Medicare rules). *See e.g.*, Sections 1814(a)(1), 1815(b), and 1833(e) of Title XVIII of the Act; *see also* 42 C.F.R. § 424.5(a)(6), 42 C.F.R. §§ 405.1018, .1028, 1030.

Unless the ALJ dismisses the hearing, the ALJ will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. 42 C.F.R. § 405.1046(a). The decision must be based on evidence offered at the hearing or otherwise admitted into the record. (*Id.*).

An Appellant may offer new evidence for the first time at the ALJ level of appeal only upon a showing of good cause why the evidence was not submitted to the QIC or a prior decision maker. The ALJ will determine whether good cause exists for the late submission of the new evidence and may only consider the evidence in making a decision if good cause is found. 42

C.F.R. § 405.1018. *See also* 42 C.F.R. §§ 405.1028 and 405.1030. This late evidence restriction does not apply to unrepresented beneficiaries. 42 C.F.R. § 405.1018(d).

II. Principles of Law

A. Statutes and Regulations

Section 1831 of the Act established a supplementary medical insurance program for the age and disabled. Coverage of medical and other health services is qualified by the overarching principles of sections 1862(a) and 1833(e) of the Act. Section 1862(a) limits Medicare payments to items or services that are “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,” notwithstanding any other provision of Title XVIII of the Act. (*See also* 42 C.F.R. § 411.15(k)(1)). Section 1833(e) of the Act requires a claim for payment under Medicare Part B to be supported by sufficient information and documentation. (*See also* 42 C.F.R. § 424.5(a)(6)).

Additionally, Section 1833(e) of the Act [42 U.S.C. § 1395l(e)] prohibits Medicare payment for any claim that lacks such information as may be necessary in order to determine the amounts due such provider.

Section 1815(a) of the Act provides that “[n]o payments shall be made to any provider unless it has furnished such information as the Secretary may request in order to determine the amounts due such provider under this part for the period with respect to which the amounts are being paid or any prior period.” *See also* 42 CFR §424.5(a)(6).

Section 1862(a)(1)(A) of the Act provides that “[n]otwithstanding any other provision of the Act, no payment shall be made for any expenses incurred for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” *See also* 42 CFR §411.15(k). The basic benefits covered by Part B are found in 42 C.F.R. § 410.3 “Scope of benefits.” Only subsection (a) is applicable to this case. It states as follows:

(a) Covered services. The SMI program helps pay for the following:

- (1) Medical and other health services such as physicians' services, outpatient services furnished by a hospital or a CAH, diagnostic tests, outpatient physical therapy and speech pathology services, rural health clinic services, Federally qualified health center services, IHS, Indian tribe, or tribal organization facility services, and outpatient renal dialysis services.
- (2) Services furnished by ambulatory surgical centers (ASCs), home health agencies (HHAs), comprehensive outpatient rehabilitation facilities (CORFs), and partial hospitalization services provided by community mental health centers (CMHCs).

Part B services also include those found in 42 C.F.R. § 410.10 “Medical and other health services” as follows:

Subject to the conditions and limitations specified in this subpart, “medical and other health services” includes the following services:

- (a) Physicians' services.
- (b) Services and supplies furnished incident to a physician's professional services, of kinds that are commonly furnished in physicians' offices and are commonly either furnished without charge or included in the physicians' bills.
- (c) Services and supplies, including partial hospitalization services, that are incident to physician services and are furnished to outpatients by or under arrangements made by a hospital or a CAH.
- (d) Diagnostic services furnished to outpatients by or under arrangements made by a hospital or a CAH if the services are services that the hospital or CAH ordinarily furnishes to its outpatients for diagnostic study.
- (e) Diagnostic laboratory and X-ray tests (including diagnostic mammography that meets the conditions for coverage specified in Sec. 410.34(b) of this subpart) and other diagnostic tests.
- (f) X-ray therapy and other radiation therapy services.
- (g) Medical supplies, appliances, and devices.
- (h) Durable medical equipment.

In regard to waiver of liability Section 1879 of the Act provides that when Medicare coverage and payment is excluded pursuant to Section 1862(a)(1) of the Act, payment may nevertheless be made for items or services, if neither the beneficiary nor the provider or supplier knew, and could not reasonably be expected to have known, that the items or services would not be covered or payable by Medicare. CMS Regulations provide that a provider or supplier will be considered to have known that items or services would not be covered or payable by Medicare if they are given direct notice of this by CMS or any of its agents, including intermediaries and carriers, by utilization review committees, or by the beneficiary's attending physician (42 C.F.R. § 411.406(b) and (c)). A provider or supplier is also considered to have notice that services are not covered if they inform the beneficiary that the services are not covered by Medicare (42 C.F.R. § 411.406(d)). A provider or supplier is also considered to have notice that services are not covered if it is clear that they could have been expected to know that from their receipt of notices from CMS or its agents, publication in the Federal Register, or based on their "knowledge of what are considered acceptable standards of practice by the local medical community" (42 C.F.R. § 411.406(e)). Notwithstanding any other provision of Title XVIII of the Act, Section 1862(a) of the Act [42 U.S.C. § 1395y(a)(1)(A)] limits the payments that may be made under Part A or Part B, stating in pertinent part that, "no payment may be made under Part A or Part B for any expenses incurred for items or services — (1)(A) which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . ." *Id.*; See also 42 C.F.R. § 411.15(k)(1.)

B. Policy and Guidance

Section 1871(a)(2) of the Act states that no rule, requirement, or statement of policy can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program unless it is promulgated as a regulation by CMS, with the only exception being national coverage determinations (NCDs). See 42 C.F.R. § 405.1060. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance describing the criteria for coverage of selected items and services in the form of manuals and local coverage determinations (LCDs), respectively.

Section 1869(f)(1) of the Act provides that National Coverage Determinations are binding upon Administrative Law Judges. *See also* 42 CFR §405.1060.

Section §1869(f)(2) of the Act provides that Administrative Law Judges will give substantial deference to local coverage determinations (LCDs), local medical review policies (LMRPs), or CMS program guidance when applicable, and if they do not follow the policy they must explain why in their decision. *See also* 42 CFR §405.1062.

CGS' LCD L34823: Tumor Treatment Field Therapy (TTFT) (Original Effective Date: For services performed on or after 10/01/2015; Revision Effective Date For services performed on or after 01/01/2017) provides the following in pertinent part:

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

ANALYSIS

The issue on appeal is whether the Appellant is entitled to Medicare payment for the TTFT (HCPCS code E0766) under the Medicare Part B. The Appellant's request was made in a timely manner and the claim satisfies the jurisdictional requirement for an ALJ Hearing before OMHA. The ALJ conducted a *de novo* review of the evidence to evaluate, without regard to the findings in the prior determinations, and determine whether the Appellant established the requirements for Medicare coverage.

The QIC denied payment, finding TTFT to be not reasonable and necessary under LCD L34823, as there was insufficient documentation to quantify the effects of the Optune device. Exh. 1, p. 4.

At this time, TTFT (E0766) is categorically denied by CGS' LCD L34823, which is the applicable Medicare policy in this case. It clearly states that "tumor treatment field therapy (E0766) will be denied as not reasonable and necessary."³ This is the case regardless of the fact that TTFT has been approved by the U.S. Food and Drug Administration.⁴ ALJs will give substantial deference to LCDs, when applicable, and if they do not follow the policy they must explain why in their decision. See 42 CFR § 405.1062.

The undersigned ALJ will not apply LCD L34823 in this case. The Appellant has provided peer-reviewed articles regarding randomized clinical trials supporting the service at issue. Exh. 2, pp. 34-193. The information produced by the Appellant more adequately describes the current state of the medical evidence than the LCD does.⁵ Indeed, the current iteration of LCD L34823 contains no references to clinical support of any kind, in stark contrast to earlier versions of the LCD that documented the references underlying the coverage determination. The Appellant's condition meets the current National Comprehensive Cancer Network (NCCN) guidelines regarding newly diagnosed GBM, particularly considering the Appellant's very recent use of temozolomide. Exh. 2, p. 30-33; Exh. 5; Hearing Recording.

As such, Medicare will pay for the Optune TTFT (HCPCS code E0766), for the dates of service of August 9, 2017, September 9, 2017, and October 9, 2017.

CONCLUSIONS OF LAW

The undersigned ALJ finds that the Appellant is entitled to coverage for the TTFT (E0766) at issue as medically reasonable and necessary to treat the Appellant's GBM. The prior determination is **REVERSED** under Section 1862(a)(1) of the Social Security Act.

³ Noridian Healthcare Solutions, LLC: Local Coverage Determination L34823: Tumor Treatment Field Therapy (TTFT) (LCD 34823)(October 2015; Updated on 04/21/2017 with effective dates 01/01/2017).

⁴ The U.S. Food and Drug Administration, in October 2015, approved an expanded indication for the Optune device by Novocure for TTF (the treatment at issue in this appeal), to treat patients, as the Appellant, with newly-diagnosed GBM. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm465744.htm>.

⁵ The randomized clinical trial published in 2015, entitled, "Maintenance Therapy with Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma," is compelling as it was a 695 patient study between July 2009 and November 2014, which resulted in the recommendation that the control group patients be allowed to receive TTFields, as the results were successful (in improvement of progression free and overall survival). Exh. 2, p. 38.

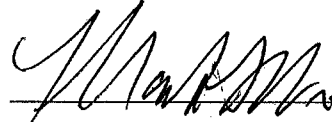
ORDER

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated:

NOV 30 2018

A handwritten signature in black ink, appearing to read "Mark Win", is written over a horizontal line.

Mark Win
Administrative Law Judge



Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

JUL 13 2018

Irvine Field Office
19 Technology Drive, Suite 200
Irvine, CA 92618
949-788-8000 (Main)
949-788-8086 (ALJ Win Team)
949-788-3660 (Fax)
866-495-7414 (Toll Free)

Date:

NOVOCURE

Attn: Rachel Castellez-Davidson
195 Commerce Way
Portsmouth, NH 03801

NOTICE OF DECISION

Appellant:

OMHA Appeal Number: 1-7506474670

Enclosed is the decision for the above case. This decision is based on the administrative record, including any evidence or testimony presented at the hearing, if one was held. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault. In addition, the decision may be reopened within 180 calendar days from the date of the decision for good cause. Good cause exists when there is new and material evidence that was not available or known at the time of the decision and may result in a different conclusion, or when the evidence that was considered clearly shows on its face that an obvious error was made at the time of the decision.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. Other parties may also appeal the decision. In addition, the Medicare Appeals Council may decide to review the decision on its own motion. If no party appeals the decision and the Medicare Appeals Council does not review the decision, the decision is binding on all parties and you and the other parties will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.

How much time do I have to file an appeal?

The Medicare Appeals Council must receive your written appeal **within 60 calendar days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 calendar days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing, except that a request for expedited review of a Part D decision may be made orally as described below. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree.

You may submit a written request for review to the Medicare Appeals Council using one of three available methods: mail, fax, or electronic filing (E-File). **Please do not submit your request for review using more than one method.** Regardless of how you file your appeal, **you must always send a copy of your written request for review to the other parties who received a copy of the decision.**

If you are filing a written request for review, you may use the enclosed *Request for Review* (form DAB-101), or you may write a letter containing the following:

- The beneficiary's/enrollee's name (and telephone number for Part D appeals);
- The beneficiary's/enrollee's health insurance claim number;
- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's decision;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's decision (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

Filing by mail:

Mail your appeal and a copy of the enclosed decision to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Filing by fax:

Fax your appeal and a copy of the enclosed decision to **(202) 565-0227**.

Filing by computer:

Using your web browser, visit the Medicare Operations Division Electronic Filing System (MOD E-File) website at <https://dab.efile.hhs.gov/mod>.

To file a new appeal using MOD E-File, you will need to register by:

- (1) Clicking **Register** on the MOD E-File home page;
- (2) Entering the information requested on the “Register New Account” form; and
- (3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at <https://dab.efile.hhs.gov/mod/users/new>. You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party’s representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

- (1) Logging into MOD E-File;
- (2) Clicking the **File New Appeal** menu button on the top right of the screen;
- (3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
- (4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the “File New Appeal – Medicare Operations Division” form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed decision. All documents should be submitted in Portable Document Format (PDF) whenever possible. Any document, including a Request for Review, will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.

Currently, the documents that may be filed electronically are the:

- (1) Request for Review;
- (2) Appointment of Representative form (OMB Form 0938-0950);
- (3) Copy of Administrative Law Judge or attorney adjudicator decision;
- (4) Memorandum or brief or other written statement in support of your appeal; and
- (5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D decision may be made by telephone to **(866) 365-8204**. You must provide the information listed in the bullet points above and a statement that you are requesting an expedited review within 60 calendar days after receipt of this notice of

decision. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file.

Please note that your request for review will only be expedited if (1) the appeal involves an issue specified in 42 C.F.R. § 423.566(b), but does not include solely a request for payment of a Part D drug that has already been furnished, and (2) the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at <http://www.hhs.gov/dab/>. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll free), if you have questions about filing an appeal.

cc:

MAXIMUS
IRE Part C Appeals-ALJ
3750 Monroe Avenue, Suite 702
Pittsford, NY 14534-1302

Blue Cross Blue Shield of Michigan
Attn: Kyra Robinson/Todd Tarkowski
P.O. Box 2627
Detroit, MI 48231

Enclosures:

OMHA-152, Decision



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Irvine, California

Appellant/ Beneficiary:	ALJ Appeal No.: 1-7506474670
PLAN: BLUE CROSS BLUE SHIELD OF MICHIGAN MUTUAL INSURANCE COMPANY	Medicare Part: C
HICN: *****0426A	Before: Mark Win Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record and at the hearing, a **FULLY FAVORABLE** decision is entered for "Appellant" and "Beneficiary".¹

PROCEDURAL HISTORY

The Appellant seeks pre-approval of the Optune device plus transducers by his Part C Medicare health plan, Medicare Plus Blue Group PPO, also doing business as Blue Cross Blue Shield of Michigan Mutual Insurance Company ("Medicare Advanced Organization"/ "MAO"). (Exh. 1). The Appellant requested pre-approval from the MAO. The request was denied by the MAO. Subsequently, the Appellant appealed to MAXIMUS Federal Services, Inc. ("MAXIMUS") who affirmed the denial. (*Id.*)

Following receipt of MAXIMUS'S unfavorable decision, the Appellant through Novocure filed a Request for Hearing before an Administrative Law Judge ("ALJ"), which was received by OMHA on May 4, 2018. (Exh. 3). The Appellant's Request for an ALJ Hearing satisfies the request for hearing requirement specified in Title 42 Code of Federal Regulations ("C.F.R.") Section 422.602(b), because the Appellant's Request for Hearing was filed within 60 days of MAXIMUS'S decision. (Exhs. 1 & 3). The amount in controversy in this matter exceeds the amount in controversy jurisdictional requirement set forth in 42 C.F.R. Sections 422.600 and 422.602(d)(1). Thus, this appeal is properly before OMHA.

¹ The terms Appellant and Beneficiary will be used interchangeably for the purposes of this decision.

On June 12, 2018, a telephonic hearing was held in this matter in Irvine, California. Ms. Stephanie Hales, Attorney/External Counsel at Sidley Austin LLP; Mr. Justin Kelly, RN, Sr. Director of Health Policy at Novocure; Mr. Dan McCoy, Manager of Case Management at Novocure; and the Appellant appeared at the hearing and argued/testified on behalf of the Appellant. Mr. James Leisen, MD, Physician Consultant; Ms. Angela Whetstone, G&A Team Lead; and Mr. Todd Tarkowski, G&A Coordinator; appeared at the hearing and argued/testified on behalf of the MAO. The Appellant submitted new medical evidence, and I admit the evidence into the administrative record because having reviewed the proposed evidence, I find good cause for its admission as the evidence bears directly on the issue to be decided in this matter and assists in more fully developing the administrative record. (42 C.F.R. § 405.1028). All of the Exhibits marked and identified in the Exhibit List were admitted into the administrative record. (Hearing CD).

ISSUES

Whether, under the Medicare Part C provisions of Title XVIII of the Social Security Act, the Medicare Advantage Organization is required to provide the Appellant/Beneficiary with pre-approval of the Optune device plus transducers.

FINDINGS OF FACT

1. A December 15, 2015, article from the *Journal of the American Medical Association*, "Maintenance Therapy with Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma" highlighted favorable clinical analyses/outcomes of Tumor-treating fields therapy. (Exh. 5, pp. 3-25).
2. With an effective date of May 1, 2016, the MAO released a newsletter, "BCN Provider News" that tumor-treating fields therapy would be covered as it "may be considered medically necessary, under the care of a physician, in the treatment of glioblastoma multiforme..." (Exh. 5, p. 54).
3. On October 12, 2017, the Appellant had a clinical consultation with a Radiation Oncology physician that suggested high-grade glioma. (Exh. 2, pp. 9-12).
4. On January 4, 2018, a physician prescribed Optune as medically necessary for treatment of glioblastoma (ICD-10: C71.1) for six months. (Exh. 2, p. 1).
5. On January 11, 2018, a delivery ticket noted the Appellant received an Optune plus transducer. (Exh. 2, p. 4).
6. On May 10, 2018, an "MRI BRAIN W AND W/O GADOLINIUM" outpatient clinical note stated that an MRI of the Appellant's brain/head found interval improvement of the enhancement and of the cystic portion of the previously present neoplasm. (Exh. 5, pp. 57-58).
7. The Evidence of Coverage ("EOC") Chapter 1, Section 1.3 provides:

The **Evidence of Coverage** is part of our contract with you about how Medicare Plus Blue Group PPO covers your care.

...

The contract is in effect for months in which you are enrolled in Medicare Plus Blue Group PPO between January 1, 2018 and December 31, 2018.

(Exh. 1, p. 155).

8. The EOC Chapter 4, Section 3.1 provides for the services that are not covered and noted that “Experimental medical and surgical procedures, equipment, and medications” may be covered only under a Medicare-approved clinical research study. (Exh. 1, p. 36).

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (“HHS”), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. (§ 1869(b)(1)(A) of the Social Security Act).

In implementing this statutory directive, the Secretary has delegated his authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. (70 Fed. Reg. 36386, 36387 (June 23, 2005)). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. (*Id.*).

A hearing before an ALJ is available only if the remaining amount in controversy is \$160.00 or more. (CMS Ruling 02-1, 67 Fed. Reg. 62478, 62480 (Oct. 7, 2002); 81 Fed. Reg. 65651 (Sep. 23, 2016)). The request for hearing is timely filed if filed within 60 days after receipt of a reconsideration decision. (42 C.F.R. § 405.1002).

B. Scope of Review

Under the Centers for Medicare and Medicaid Services’ (“CMS”) implementation policy for the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. Law 106-554, app. F, 114 Stat. 2763, 2763A-463, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”), Pub. Law 108-173, 117 Stat. 2066, all initial determinations by CMS contracted Carriers prior to January 1, 2006, are governed by the ALJ hearing procedures set forth at 20 C.F.R. Sections 404.929 through 404.961 and 42 C.F.R. Section 405.855. (70 Fed. Reg. 11420, 11424-26 (Mar. 8, 2005)).

The issues before the administrative law judge include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in the appellant’s favor. (42 C.F.R. § 405.1032(a)).

C. Standard of Review

The ALJs at OMHA conduct a “de novo” review and issue decisions based on the hearing record. (42 C.F.R. § 405.1000(d)).

II. Principles of Law

A. Statutes and Regulations

The Medicare Part C program entitles a beneficiary to have Medicare services furnished or paid for by MAOs through Medicare Advantage Plans. (42 C.F.R. § 422.1(b)). Generally for reimbursement under Medicare, the basic requirement of any service is that it must be; “reasonable and necessary” “treatment” of “illness” to improve function. (§ 1833(e) of the Social Security Act). As a further requirement, the C.F.R. observes that Medicare Advantage health plans must pay for medical services if Medicare would pay for it. (42 C.F.R. § 422.101).

Under Medicare Part C, a Medicare Advantage Plan must pay for those items and services (other than hospice benefits) for which benefits are available under Part A and Part B. (42 C.F.R. § 422.100(c)(1) & Title XVIII, Social Security Act, § 1852). A Medicare Advantage Plan can provide supplemental benefits that are not covered under Part A and Part B. (42 C.F.R. § 422.100(c)(2) & Title XVIII, Social Security Act, § 1852).

Section 1833(e) of the Social Security Act (“Act”) states that no payment shall be made to any provider of service unless supported by sufficient information and documentation. (42 C.F.R. § 424.5(a)(6)).

Section 1862(a)(1) of the Act limits Medicare coverage and payment to items and services that are reasonable and necessary for the diagnosis and treatment of an illness or injury, or to improve the functioning of a malformed body member. (42 C.F.R. § 411.15(k)(1)).

Section 1879 of the Act provides that when Medicare excludes payment and coverage pursuant to section 1862(a)(1) of the Act, payment may nevertheless be made for the items or services, if neither the beneficiary nor the provider or supplier knew, or could not reasonably be expected to have known, that the items or services would not be covered or payable by Medicare. (42 C.F.R. § 411.406).

Section 1812(a)(2)(A) of the Act provides that the benefits provided to an individual by the insurance program under this part shall consist of entitlement to have payment made on his behalf or, in the case of payments referred to in section 1814(d)(2) to him (subject to the provisions of this part) for post-hospital extended care services for up to 100 days during any spell of illness, and (B) to the extent provided in subsection (f), extended care services that are not post-hospital extended care services.

42 C.F.R. 422.112(a) titled “Access to services” provides “Rules for coordinated care plans”:

An MA organization that offers an MA coordinated care plan may specify the networks of providers from whom enrollees may obtain services if the MA organization ensures that all covered services, including supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan.

B. Policy and Guidance

ALJs are bound by statutes, regulations, national coverage determinations (“NCDs”), and CMS Rulings. (42 C.F.R. §§ 405.1060(a)(4) and 405.1063.) An ALJ is not bound by a local coverage determination (“LCD”) or Medicare program guidance such as program memoranda and manual instructions, “but will give substantial deference to these policies if they are applicable to a particular case.” (42 C.F.R. § 405.1062(a).) If an ALJ declines to follow a policy in a particular case, the ALJ must explain the reasons why the policy was not followed. (*Id.* at § 405.1062(b).)

Local Coverage Determination (“LCD”) L34823:

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

ANALYSIS

The Appellant is seeking pre-approval of the Optune device plus transducers from the MAO. In MAXIMUS’S unfavorable decision, it relied on LCD L34823 and stated that Medicare does not consider tumor-treatment field therapy to be medically necessary. (Exh. 1, p. 5).

Health plans are required to cover a service if it would be covered by Medicare. (42 C.F.R. § 422.101 & EOC Ch. 3, Section 1.2). LCD L34823 provides: “Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.” An ALJ is not bound by a LCD, “but will give substantial deference to these policies if they are applicable to a particular case.” (42 C.F.R. § 405.1062(a)). If an ALJ declines to follow a policy in a particular case, the ALJ must explain the reasons why the policy was not followed. (*Id.* at § 405.1062(b).)

Here, the decision is favorable to the Appellant. While the lower levels found against the Appellant because of the LCD language that tumor treatment field therapy will be denied as not reasonable and necessary, an ALJ is not bound by an LCD and may consider other factors. (Exh. 1, p. 5; 42 C.F.R. § 405.1062(a); 42 C.F.R. § 405.1062(b)). In this case, after giving LCD L34823 due consideration, the Appellant has persuaded the undersigned to decline to follow the LCD based on ample evidence provided in this particular case. The undersigned specifically declines to follow LCD L34823 for this Appellant in light of the up-to-date favorable analyses of the relevant clinical trial that was noted in the *Journal of the American Medical Association* (Exh. 5, 3-25), the Appellant’s favorable response to the treatment thus far (*Id.* at 5-58), and the fact that the therapy is currently covered for the MAO’s commercial subscribers (*Id.* at 54), all of which support the therapy’s overall safety and effectiveness for this particular Appellant and for the specific time period at issue in this case. The MAO’s literature specifically described the tumor-treatment field therapy as being “considered medically necessary, under the care of a physician, in the treatment of glioblastoma multiforme.” (*Id.*) In addition, the prescribing

physician stated that the treatment was medically necessary and confirmed that the Appellant had a diagnosis of glioblastoma. (Exh. 2, p. 1). Accordingly, the Appellant is entitled to pre-approval of the Optune device plus transducers.

CONCLUSIONS OF LAW

Under the Medicare Part C provisions of Title XVIII of the Social Security Act, the Medicare Advantage Organization is required to provide the Appellant/Beneficiary with pre-approval of the Optune device plus transducers.


ORDER

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

JUL 13 2018

Dated: _____



Mark Win
Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Irvine, California

Appeal of:	OMHA Appeal No.: 1-7506474670
Enrollee:	Medicare: Part C
Medicare No.:	Before: Mark Win Administrative Law Judge

EXHIBIT LIST

EXHIBIT NUMBER	DESCRIPTION	PAGE NUMBERS
1	Organization Determination, MAO Reconsideration and Part C QIC Reconsidered Decision Procedural Documents	248
2	Medical Records/Evidence received by MAO and CMS contractors	12
3	Request for ALJ Hearing	2
4	OMHA Proceedings	30
5	Post-Hearing Documents	58



**U.S. Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Arlington, Virginia**

Appeal of:

ALJ Appeal No: **1-6339385011**

Beneficiary: **Same**

Medicare Part C

HICN: **xxx-xx- 1908A**

Before : Mary F. Withum
U.S. Administrative Law Judge

DECISION

After carefully considering the entire record and testimony presented at the hearing, a **FAVORABLE** decision is entered in the appeal of the Beneficiary,

PROCEDURAL HISTORY

HEALTH NET HEALTH PLAN OF OREGON (Health Net) the Beneficiary's Medicare Part C Plan, denied the request for pre-approval coverage for tumor treatment field therapy (TTFT). Upon request for reconsideration, MAXIMUS Federal Services, the Qualified Independent Contractor (QIC), issued an unfavorable decision.

The Office of Medicare Hearings and Appeals, (OMHA) received the Beneficiary's timely request for a hearing. The amount in controversy satisfies the jurisdictional requirement for a hearing pursuant to Title XVIII of the Social Security Act, (the Act) §1869(b)(1)(E).

On July 6, 2017, the Administrative Law Judge held a telephone hearing from the Office of Medicare Hearings and Appeals. Appearing on behalf of the Beneficiary was Novocure's Health Plan Analyst representative Dan McCoy. Appearing for Health Net was Rosy King.

ISSUE

The issue is whether Health Net must pre-approve coverage for TTFT, pursuant to Medicare Part C provisions of Title XVIII of the Act, as amended.

FINDINGS OF FACT

The QIC held that Medicare does not cover TTFT. Specifically, the requested therapy is statutorily non-covered pursuant to the Local Coverage Determination (LCD): Tumor Treatment

Field Therapy (L34823). Therefore, the QIC decided that the Plan did not have to pre-approve the TTFT. (Ex. 1, p. 6)

The Beneficiary was enrolled in Part C Medicare coverage through Health Net and sought pre-approval for the TTFT for the management of his condition of glioblastoma multiforme (GBM). On March 22, 2017, citing to LCD L34823, Health Net issued a denial of the Beneficiary's request for the TTFT as the services was not a covered benefit. Specifically, the Plan argued that electric field therapy such as Optune TTFT was considered investigational/experimental by Health Net, as such, it is benefit exclusion. (Ex. 1, p. 48)

The Plan's Explanation of Coverage (EOC), for 2017 Chapter 4, Medical Benefits Chart, (what is covered and what you pay), indicated that services considered not reasonable and necessary according to standards of Original Medicare and experimental procedures and items are not covered by Medicare. Experimental items are those determined by the Plan and Original Medicare to not be generally accepted by the medical community. (Ex. 1, p. 237)

In the March 11, 2017 physician letter, Dr. _____ indicated that the 67-year-old male Beneficiary was recently diagnosed with GBM on November 7, 2016. His history with the disease started when he was having difficulty driving and would sometimes hit the curb. He subsequently went to the emergency room for evaluation. A November 3, 2016 MRI revealed primary cyst malignancy, so the Beneficiary had a follow up done with neurosurgery and underwent surgery on November 7, 2016 with a pathology showing positive for GBM. He began chemotherapy on December 1, 2016 and completed the last cycle on January 22, 2017. Thereafter on February 18, 2017 he began his first dose of adjuvant temozolomide (TMZ) which he tolerated well. He had a follow up MRI on February 23, 2017 that showed the enhancement was present around the surgical cavity. After discussing further treatment options with the Beneficiary, the physician prescribed Optune in combination with TMZ as this was best option for treating his GBM. (Ex. 2, pp. 68-72)

The April 27, 2017 physician letter of medical necessity from Dr. _____ indicate that to treat the Beneficiary's recent diagnosis of GBM, which is an orphan disease (only affecting fewer than 200,000 people nationwide), he previously tried the standardize treatments such as surgery and chemotherapy; however, it was now appropriate that he begin the Optune therapy in conjunction with the TMZ. Dr. _____ indicated that Optune and adjuvant TMZ was now a National Comprehensive Network (NCCN) Category 2A recommendation following post-operative standardized radiation with concurrent temozolomide. (Ex. 1, pp. 17-18)

In the October 5, 2015 FDA News Release letter, the FDA approved and expanded indication for Optune device to treat patients with newly-diagnosed GBM. It is to be given along with the chemotherapy drug TMZ following standard treatments that include surgery, and radiation therapy and chemotherapy used together. In the clinical study used to support the expanded indication, patients treated with the device and TMZ lived on average three months longer than those treated with drug alone.

<https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm465744.htm>

Pursuant to the FDA website, the oncology company Novocure provided detail clinical data to support its use in conjunction with TMZ for newly diagnosed GBM patients, as well as instructions for use of Optune. www.accessdata.fda.gov/cdrh_docs/pdf10/p100034s013c.pdf

Pursuant to NCCN website, the NCCN categories for evidence of coverage detailed that: Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate. **Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.** Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate. Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate. https://www.nccn.org/professionals/physician_gls/categories_of_consensus.asp

The report titled the NCCN Central Nervous System Cancers indicates that in treating GBM there is a “good performance status” with standard brain radiation therapy and concurrent TMZ and adjuvant TMZ and alternating electric field therapy. It was noted that “all recommendations are category 2A unless otherwise indicated.” (Ex. 1, pp. 73-74)

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

An individual or organization dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act §1869(b)(1)(A).

In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. 70 Fed. Reg. 36386, 36387 (June 23, 2005).

For requests filed in calendar years 2010 through 2012, the minimum amount remaining in controversy required for an ALJ hearing is \$130.00 (following application of any co-insurance or deductible). See §1869(b)(1)(E) of the Act, 74 Fed. Reg. 48976 (Sept. 2, 2009). See also 42 CFR §405.1006(b), 42 CFR §405.1006(d)(1)(ii).

B. Scope of Review

The ALJ appeals process is governed by 42 CFR §§405.1000 *et seq.* 42 CFR §405.1032 provides that the issues before the administrative law judge include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in the appellant's favor. However, if evidence presented before or during the hearing causes the administrative law judge

to question a fully favorable determination, he or she will notify the appellant and will consider it an issue at the hearing.

C. Standard of Review

The ALJ conducts de novo review. 42 CFR §405.1000(d) and Section 557 of the Administrative Procedure Act. De novo review requires the ALJ to independently review and evaluate the evidence without regard to the findings of prior determinations.

It is the appellant's burden to prove each element of a Medicare claim by preponderance of the evidence. See Sections 1814(a)(1), 1815(b), and 1833(e) of the Act; 42 CFR §424.5(a)(6), 42 CFR §405.1018, 42 CFR §405.1028, and 42 CFR §405.1030.

An appellant may offer new evidence for the first time at the ALJ level of appeal only upon a showing of good cause why the evidence was not submitted to the QIC or a prior decision maker. The ALJ will determine whether good cause exists for the late submission of the new evidence. See 42 CFR §405.1018, 42 CFR §405.1028 and 42 CFR §405.1030. The good cause requirement does not apply to unrepresented beneficiaries. See 42 CFR §405.1018(d).

I. Principles of Law

Sections 1851 through 1859 of the Act offers beneficiaries the option to enroll in a participating Medicare Advantage plan (MA). In this situation, Medicare pays the respective MA a set amount of money to deliver the same Medicare benefits that the Beneficiary would otherwise be entitled to in a traditional "fee-for-service" program.

The aforementioned sections of the Act have been implemented under the Code of Federal Regulations, at 42 CFR. §422.100, which provides that managed care beneficiaries are considered "locked in" and must obtain all the Medicare covered services and supplies from their managed care entity. Each MA must provide coverage for all services covered by Part A and Part B of Medicare. 42 CFR §422.101(a).

Additionally, 42 CFR §422.101(b) list the exceptions to the "lock-in" rule, which would require the MA to provide Medicare coverage for urgently needed medical care, a medical emergency, for services the MA approved in advance, or for medically reasonable and necessary services which are covered by Medicare that the MA refused to provide.

42 CFR §411.15 Medicare does not pay eye exams for the purpose of prescribing, fitting, or changing eyeglasses or contact lenses for refractive error only. Medicare does not pay for procedures performed in the course of any eye exam to determine the refractive state of eyes. Refractive procedures are not covered even when done in connection with otherwise covered diagnosis or treatment of illness or injury.

Notwithstanding any other provision of Title XVIII, § 1862(a) of the Act [42 U.S.C. § 1395k(2)(B)] allows coverage and payment for only those items and services that are reasonable and medically necessary. Additionally, § 1833(e) of the Act [42 U.S.C. § 1395l(e)] prohibits

Medicare payment for any claim that lacks such information as may be necessary in order to determine the amounts due such provider.

A. Policy and Guidance

§1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than National Coverage Determinations (NCDs), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. *See also* 42 C.F.R. §405.860. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local coverage determinations (LCDs).

§1869(f)(2) of the Act provides that Administrative Law Judges will give substantial deference to local coverage determinations (LCDs), local medical review policies (LMRPs), or CMS program guidance when applicable, and if they do not follow the policy they must explain why in their decision. *See also* 42 CFR §405.1062.

- Specific to this instance case is LCD L34823 titled “Tumor Treatment Field Therapy”, and states that: Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

ANALYSIS

At the hearing, Mr. McCoy argued that Medicare coverage is appropriate in this case because in October 2015 the FDA approved Optune with TMZ for newly diagnosed GBM patients. Moreover, in July 2016 the NCCN guidelines showed that Optune w/ TMZ was now a recommended 2A category, i.e. there was uniform NCCN consensus that the intervention is appropriate. Mr. McCoy further argued that there had been over a dozen favorable decisions rendered by other ALJs based on the FDA’s newly expanded indication of Optune for patients with newly-diagnosed GBM.

Health Net representative, Ms. King, argued that after the Plan reviewed this case, it determined that it was a benefit of exclusion issue pursuant to the governing LCD.

After careful review of the record and testimonies at the hearing, the undersigned has determined that although LCD L34823 indicates that the requested Optune therapy was statutorily non-covered, §1869(f)(2) of the Act provides that an ALJ has to only give “substantial deference” to a LCD. Hence, because there is now proof that the FDA has approved and expanded the indication for Optune device to treat patients with newly-diagnosed GBM; the undersigned will not follow the above-mentioned LCD. Specifically, the 67-year-old male Beneficiary was recently diagnosed with GBM on November 7, 2016. He subsequently underwent surgery and then began chemotherapy on December 1, 2016. Thereafter on February 18, 2017 he began his first dose of adjuvant TMZ which he tolerated well. However, a follow up MRI on February 23, 2017 showed the enhancement was present around the surgical cavity, so it became medically

necessary to now try the Optune therapy in conjunction with TMZ as this was best option for treating the Beneficiary's GBM.

Based on the above, the undersigned finds that Medicare coverage for Optune is appropriate in this case. Therefore, Health Net is obligated to pre-approve coverage for TTFT.

CONCLUSIONS OF LAW

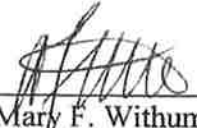
Health Net is obligated to pre-approve the TTFT.

ORDER

Health Net is **DIRECTED** to process the claim in accordance with this decision.

09/11/2017

Date
Trs/



Mary F. Withum, U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, Missouri

1012610

Appeal of:	Novocure	ALJ Appeal No.:	1-6221975819
Beneficiary:		Medicare Part:	C
PLAN:	Excellus Health Plan		
HICN:	****4271A	Before:	Kimberley Woodyard U.S. Administrative Law Judge

DECISION

Upon a *de novo* review of the record in this case, and following hearing, this Administrative Law Judge enters a **FAVORABLE** decision for the Appellant Enrollee, who is entitled to coverage for the Tumor Treatment Field Therapy.

Procedural History

This appeal is before this Administrative Law Judge following prior adverse decisions of the Plan and the Independent Review Entity, both of which denied the Appellant's claim for payment of the services. The IRE reconsideration decision was issued on April 17, 2017, after which the Appellant filed a request for hearing before an Administrative Law Judge, on May 9, 2017.

Inasmuch as the request was timely and the amount in controversy meets the jurisdictional requirements for an ALJ hearing, 42 C.F.R. §§ 417.600, 422.600, 422.602, this ALJ has jurisdiction to conduct the *de novo* review and issue a decision, 42 C.F.R. § 422.602.

Hearing on this matter was held on June 20, 2017, at which Ms. Tanya Lane, Novocure's case manager appeared. Observing from her office were other case managers with Novocure: Daniel McCoy, Shannon Fisher, and Marcia Spainhower. Excellus Health Plan appeared by Mr. Shea Kolar, Esq., Associate Counsel, and Dr. Richard Lockwood, Medical Director. Exhibits 1-5 were received into evidence over no objection. Following testimony and argument, the record was closed and the hearing concluded.

Issues

The issue is whether all contract coverage requirements have been met warranting payment under Title XVIII of the Social Security Act.

Findings of Fact

This Judge finds the following facts to be established by the evidence in the record:

~ is a seventy-two year old woman who suffers from a malignant glioblastoma. (Exh. 2, p. 36; *see generally* Exh. 3). Glioblastoma is an “orphan disease,” with limited treatment options. (Exh. 2, p. 38). *See generally* Wong, et al., *Dexamethasone exerts profound immunologic interference on treatment efficacy for current glioblastoma*, BJcancer.com /DOI:10.1038/bjc.2015.238 (British Journal of Cancer) (Exh. 4, p. 79, *et. seq.*).

On April 19, 2016, ~ endured a resection of a left parieto-occipital glioblastoma. (Exh. 3, p. 3). She finished radiation therapy and Temodar on July 26, 2017, completed her first maintenance Temodar in September, but became ill and was twice hospitalized with extreme fatigue, failure to thrive, and pneumonia. (Exh. 3, p. 3). At a physician visit on December 6, 2017, her MRI scan showed a stable left temporal mass with stable mass effect and no new lesions. Her right sided meningioma was also stable in that interval. The mass had significantly increased in size since April 20, 2016. (Exh. 3, p. 4). Her physician wanted her to initiate the Optune therapy as soon as possible. (Exh. 3, p. 4).

~ was on Temedor, and had been in the past. (Exh. 3, pp. 3, 4). Temedor is a brand name for Temozolomide.

On December 7, 2016, ~'s physician signed an Optune Prescription Form prescribing Optune treatment, the treatment to start on December 12, 2016 (Exh. 3, p. 1). He believed that the Optune treatment, combined with temozolomide, was, and is for ~, the best option for treating glioblastoma. (Exh. 2, p. 37).

Optune treats cancer by using tumor-treating fields (TTF) to interfere with the division of malignant cells. It is locally or regionally delivered, using alternating electric fields to disrupt the rapid cell division exhibited by cancer cells. (Exh. 2, p. 37). Optune received pre-market approval from the FDA for treatment of glioblastoma in April 2011,¹ based upon the result of a large randomized, controlled trial of patients with recurrent GBM. *Id.* The overall survival and progression-free survival to chemotherapy with minimal toxicity and an improvement in patients quality of life, is demonstrated, compared to that of chemotherapy. *Id.* Subsequently, in 2015, the FDA approved Optune for newly diagnosed glioblastoma in combination with temozolomide.² The trials showed superior efficacy in both progression-free survival as well as overall survival. *Id.*

¹ http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100034a.pdf.

² http://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034S013a.pdf.

On December 15, 2015, the Journal of the American Medical Association (JAMA) published an article analyzing the results of a phase III clinical trial related to TTFT.³ (Exh. 4, p. 5 *et. seq.*). The analysis of the clinical trial showed that adding TTFT to maintenance temozolomide in a population with new onset glioblastoma “significantly prolonged progression-free and overall survival.” *Id.* After conclusion of the study, patients in the control group with ongoing maintenance therapy were offered TTFT therapy. *Id.*

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with the decisions of the Medicare contractor and the Qualified Independent Contractor is entitled to a hearing before the Secretary of the Department of Health and Human Services, Social Security Act § 1869(b)(1)(A), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner, 42 C.F.R. §§ 422.600, 422.602. The request for hearing is timely if filed within sixty days after receipt of a Qualified Independent Contractor decision. 42 C.F.R. § 422.602. The minimum amount in controversy required for hearing before an Administrative Law Judge are published in the Federal Register.

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the Appellant’s favor. 42 C.F.R. § 405.1032(a).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue and makes a decision based on the hearing record. 42 C.F.R. § 405.1000(d).

II. Principles of Law

A. The Statutes and Regulations

Sections 1812 and 1813 of the Act establish the scope of benefits of the hospital insurance program under Medicare Part A. Section 1814 establishes conditions for, and limitations on, payment for services furnished by providers. Medicare coverage for hospitalization includes payment for the services generally available in a hospital: bed and board, nursing services and other related services, use of hospital facilities, medical social services, drugs, supplies and equipment, diagnostic or therapeutic items or services, and medical or surgical services provided by certain interns and residents pursuant to section 1861(b) of the Act.

³ Stupp, Roger, M.D. et al., *Maintenance Therapy With Tumor-Treating Field Plus Temozolomide vs Temozolomide Alone for Glioblastoma A Randomized Clinical Trial*, 314 JAMA 2535 (2015).

In addition, section 1861 defines hospitals to include institutions which provide “therapeutic services for medical diagnosis, treatment and care of injured, disabled, or sick persons, or rehabilitation or injured, disabled or sick persons.” Section 1862(a)(1)(A), prohibits Medicare payments for anything which is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

In the event the services are found to be “not medically reasonable and necessary” or “custodial in nature” under section 1862(a)(1) or (a)(9) of the Act, section 1879 provides for limitation on liability for Medicare payments. If the beneficiary had no knowledge that the services would not be covered, but the provider of the services did, then the provider is liable and cannot seek or retain payment by the beneficiary. The regulations at 42 C.F.R. § 411.400 *et seq.* and HCFA Ruling 95-1 address how to determine if the beneficiary or provider/supplier had the requisite degree of knowledge to make them liable under section 1879. *See also* CMS, Medicare Claims Processing Manual (MCPM), Internet-Only Manual Pub. 100-4, Ch. 30, § 20. In general, the existence of a notice, manual, or community medical standard is sufficient to constitute notice as applicable to the provider. 42 C.F.R. § 411.406.

B. Policy and Guidance

The Social Security Act vests in the Secretary the authority to make coverage decisions. Under that authority, CMS issues National Coverage Determinations (NCDs) that state whether specific medical items, services, treatment procedures, or technologies may be paid for by Medicare. In the absence of a specific NCD, the Medicare contractor is responsible for determining whether an item or service is reasonable and necessary. (See preface to Coverage Issues Manual (reprinted at 54 Fed. Reg. 34555 (Aug. 21, 1989)). Accordingly, in addition to looking to the binding statutory and regulatory authority, this ALJ must accord substantial deference to manuals, program memoranda and other issuances issued by the Center for Medicare and Medicaid Services (CMS) and its carriers and intermediaries. 42 C.F.R. § 405.1062. Thus, the ALJ looks to the Local Coverage Determinations (LCD), if any, and the Medicare Benefit Policy Manual.

Historically, in making coverage determinations, CMS has interpreted the terms “reasonable and necessary” to mean that the item or service in question is safe and effective and not experimental. CMS has further determined that the relevant tests for applying these terms are whether the item or service has been proven safe and effective based on authoritative evidence, or alternatively, whether the item or service is generally accepted in the medical community as safe and effective for the condition for which it is used. 54 Fed. Reg. 4304 (Jan. 30, 1989); 60 Fed. Reg. 48417 (Sept. 19, 1995); see also 52 Fed. Reg. 15,560 (Apr. 29, 1987). Indeed, CMS has provided guidance in the *Medicare Program Integrity Manual* (CMS Pub. 100-08) (*MPIM*) to assist contractors in developing LCDs to aid in creating relevant tests and guidance. The *MPIM* contemplates that, in making a determination as to whether an item or service is reasonable and necessary, contractors will analyze whether the item or service is safe and effective, and not experimental or investigational. *MPIM*, Ch. 13 at § 13.5.1. Contractors shall consider a service reasonable and necessary if the contractor determines that the service is:

- Safe and effective;

- Not experimental or investigational; and
- Appropriate, including the duration and frequency that is considered appropriate for the service.

The *MPIM* further instructs contractors to base LCDs on the strongest evidence available at the time the determination is issued. In order of preference, this includes:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and ALJs and the Medicare Appeals Council are not bound by CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. 42 C.F.R. § 405.1062(a).

- General acceptance by the medical community (standards of practice), supported by sound medical evidence based on:

- o Scientific data or research studies published in peer-reviewed medical journals;
- o Consensus of expert medical opinion (i.e., recognized authorities in the field);
- or
- o Medical opinion derived from consultations with medical associations or other health care experts.

Id. at § 13.7.1. The Manual further explains:

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

Id.

There is a Local Coverage Determination stating CMS' guidance for Tumor Treatment Field Therapy: Noridian Administrative Services, Local Coverage Determination, LCD L34823, and Tumor Treatment Field Therapy (July 1, 2016). This LCD provides, without elucidation, that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. The related Policy Article states that tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit and must meet the reasonable and necessary requirements set out in the related LCD to be eligible for reimbursement. Noridian Admin. Serv., Local Coverage Article for Tumor Treatment Field Therapy Article A52711 (Article A52711) (Oct. 2015). The most recent literature cited in the LCD was published in 2013.⁴

⁴ Oddly, the 2016 LCD (an up-date from the 2015 version, which is not markedly distinguishable) includes no up-dates of the literature. The latest LCD, effective January 1, 2017, not only fails to up-date the literature, it omits it.

C. The Plan

As provided in the Social Security Act, the plan must cover all services covered by original Medicare and must follow original Medicare's coverage rules. (Exh. 1, p. 48-49). The plan provides a listing of covered services in Chapter 4. (Exh. 1, p. 43). Experimental procedures, *i.e.*, procedures determined by the plan or original Medicare to not be generally accepted by the medical community, are not covered. (Exh. 1, p. 79).

Analysis

The issue is whether the Appellant's services are entitled to coverage. Medicare Advantage plans must pay for a medical service if original Medicare would cover it. 42 C.F.R. § 422.101. The Plan may also offer additional benefits to those covered by original Medicare if it so chooses. 42 C.F.R. § 422.102. The Plan in this case covers all services provided by original Medicare.

There is no National Coverage Determination specific to tumor treatment field therapy. This ALJ, therefore, looks to the relevant LCD for guidance. ALJs are not bound by LCDs and will give substantial deference to the policies if they are applicable to a particular case. 42 C.F.R. § 405.1062. If an ALJ declines to follow an LCD in a particular case, the ALJ must explain the reasons why the policy was not followed. *Id.*

In this case, this ALJ declines to follow LCD L34823 for multiple reasons. The therapy has been shown to be safe and effective for use in patients with recurrent glioblastoma (after chemotherapy, radiation and/or surgery has been tried without sufficient success, all as here,) and it is medically reasonable and necessary to treat the patient in this condition.

The relevant LCD states that tumor treatment field therapy will be denied as not reasonable and necessary. However, the Information and Basis of Decision section of the applicable version LCD showed that the most recent literature reviewed for purposes of the LCD's formation was published in 2013. If additional or more recent literature was reviewed, it is not listed in the LCD. In any event, the advancement of medicine and science can sometimes outpace the current or relevant version of an LCD. Subsequently reported data from the FDA, phase III clinical trials, and NCCN guidelines is available to this ALJ for review and analysis, and shows the LCD, at best, is behind the medical literature curve – at least as applied to this patient.

The more helpful and relevant Medicare guidance in this instance is the *Medicare Program Integrity Manual* (CMS Pub. 100-08) (*MPIM*), which provides the more appropriate and helpful guidance for making a determination as to whether an item or service is reasonable and necessary, and not experimental or investigational. *MPIM*, Ch. 13 at § 13.5.1.

Applying that guidance, this ALJ first finds that the Optune device received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011. On October 5, 2015, the FDA gave premarket approval for use of Optune in patients with newly diagnosed glioblastoma. The FDA website explains that premarket approval (PMA) entails the following:

PMA is the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to

marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).⁵

While FDA premarket approval does not establish that the device is medically reasonable and necessary pursuant to Medicare requirements, it does ensure that the FDA has closely examined the device and its application. In this case, the FDA determined that sufficient scientific evidence existed to provide the FDA with assurance that the device was safe and effective for its intended use both in patients with recurrent and newly diagnosed glioblastoma. From this perspective, the use of the device meets Medicare guidance requiring that a device be proven safe and effective based on authoritative evidence.

The FDA approval, along with the other evidence below, also helps shows that the device is safe, and not experimental or investigational Medicare does not pay for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. Act § 1862(a)(1). To be reasonable and necessary, the procedure must be safe and effective and not experimental.

Second, this ALJ has reviewed clinical studies in the record related to the use of the Optune device. Results from a phase III clinical trial utilizing TTFT in patients with recurrent glioblastoma was shown to have equivalent efficacy when compared to the best physician's choice for chemotherapy. With respect to patients newly diagnosed with glioblastoma, results of a phase III study released in a December 15, 2015, JAMA article showed that adding TTFT to maintenance temozolomide significantly prolonged progression-free and overall survival. Significantly, patients in the control group in the JAMA-reported study crossed over to the combined therapy group for TTFT treatment due to the improvement in outcomes seen. The results from these phase III trials also led to FDA approval for the Optune device. Again, these trials showed that the Optune device was safe, non-investigational and effective. It is noteworthy that the 2015 study contains proof of efficacy. In contrast, the LCD lacks any substantive guidance, analysis, or even recent citation to medical authority. In addition, these trials showed that the Optune device was appropriate for s needs, specifically the treatment of recurrent glioblastoma.

Third, the use of TTFT is generally accepted by the medical community. In the 2015 version of the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology Central Nervous System Cancers guidelines, alternating electric field therapy is a treatment option suggested for glioblastoma. This suggestion was found in a treatment guideline from a national cancer organization, not evidence based on an individual physician treating a single patient in a clinical setting. As such, TTFT treatment is generally accepted in the medical community as safe and effective for the treatment of recurrent glioblastoma.

Overall, a review of the literature available showed that the Optune device received FDA premarket approval, showing that it was safe and effective and not investigational/experimental.

⁵<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm>

The use of the Optune device in a population with recurrent glioblastoma was proven effective and appropriate through a phase III clinical trial; and the use of the Optune device appears in national cancer treatment guidelines for treatment of glioblastoma, showing general acceptance by the medical community. A number of commercial health plans also now cover TTFT.

For the reasons stated above, this ALJ finds that Optune (TTFT) has been shown to be safe and effective, and is not experimental. Medicare coverage is thus available for tumor treatment field therapy. Accordingly, the Plan, too, must cover these medically reasonable and necessary services for the treatment of Mr. [redacted]'s condition.

Conclusions of Law

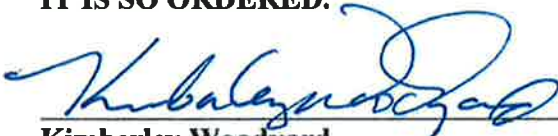
Contract coverage exists for the Optune Tumor Treatment Field Therapy.

Order

The Medicare Contractor is DIRECTED to process the request in accord with this decision.

IT IS SO ORDERED.

Dated: JUN 27 2017


Kimberley Woodyard
U.S. Administrative Law Judge



**Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, Missouri**

Appeal of:	ALJ Appeal No.: 1-6221975819
Beneficiary:	Medicare Part: C
PLAN: Excellus Health Plan	
HICN: ****4271A	Before: Kimberley Woodyard U.S. Administrative Law Judge

EXHIBIT LIST¹

Exhibit	Description	Pages
1	Evidence of Coverage	1-440
2	Initial, Redetermination and Reconsideration Documents	1-59
3	Medical Records/Evidence Received by CMS Contractors	1-17
4	Clinical Guidelines, JAMA article, Optune Data	1-89
5	Request for Hearing	1-4
6	OMHA Proceedings: <ul style="list-style-type: none">• Notice of Hearing and blank Response Form• Responses to NOH	1-24

Dated: June 27, 2017

¹ Some materials in the exhibited record may be dual sided. The second side of a dual-sided page is not included in the page count for the page number range.



Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

Kansas City Field Office
601 East 12th Street, Suite 221
Kansas City, MO 64106
816-599-3300 (Main) (Main)
816-599-3236 (ALJ Woodyard Team)
816-527-0115 (Fax)
844-566-6258 (Toll Free)

Date: June 27, 2017

SHANNON FISHER
NOVOCURE
195 COMMERCE WAY
PORTSMOUTH, NH 03801

NOTICE OF DECISION

Appellant:

OMHA Appeal Number: 1-6221975819

Enclosed is the decision for the above case. This decision is based on the administrative record, including any evidence or testimony presented at the hearing, if one was held. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault. In addition, the decision may be reopened within 180 days of the decision for good cause. Good cause exists when there is new and material evidence that was not available or known at the time of the decision and may result in a different conclusion, or when the evidence that was considered clearly shows on its face that an obvious error was made at the time of the decision.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. Other parties may also appeal the decision. In addition, the Medicare Appeals Council may decide to review the decision on its own motion. If no party appeals the decision and the Medicare Appeals Council does not review the decision, the decision is binding on all parties and you and the other parties will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.

How much time do I have to file an appeal?

The Medicare Appeals Council must receive your written appeal **within 60 calendar days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 calendar days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing, except that a request for expedited review of a Part D decision may be made orally as described below. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree.

You may submit a written request for review to the Medicare Appeals Council using one of three available methods: mail, fax, or electronic filing (E-File). **Please do not submit your request for review using more than one method.** Regardless of how you file your appeal, **you must always send a copy of your written request for review to the other parties who received a copy of the decision.**

If you are filing a written request for review, you may use the enclosed *Request for Review* (Form DAB-101), or you may write a letter containing the following:

- The beneficiary's/enrollee's name (and telephone number for Part D appeals);
- The beneficiary's/enrollee's health insurance claim number;
- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's dismissal;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's decision (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

Filing by mail:

Mail your appeal and a copy of the enclosed decision to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Filing by fax:

Fax your appeal and a copy of the enclosed dismissal to **(202) 565-0227**.

Filing by computer:

Using your web browser, visit the Medicare Operations Division Electronic Filing System (MOD E-File) website at <https://dab.efile.hhs.gov/mod>.

To file a new appeal using MOD E-File, you will need to register by:

- (1) Clicking **Register** on the MOD E-File home page;
- (2) Entering the information requested on the "Register New Account" form; and
- (3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at <https://dab.efile.hhs.gov/mod/users/new>. You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party's representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

- (1) Logging into MOD E-File;
- (2) Clicking the **File New Appeal** menu button on the top right of the screen;
- (3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
- (4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the "File New Appeal – Medicare Operations Division" form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed decision. All documents should be submitted in Portable Document Format (PDF) whenever possible. Any document, including a Request for Review, will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.

Currently, the documents that may be filed electronically are the:

- (1) Request for Review;
- (2) Appointment of Representative form (OMB Form 0938-0950);
- (3) Copy of Administrative Law Judge or attorney adjudicator decision;
- (4) Memorandum or brief or other written statement in support of your appeal; and
- (5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D decision may be made by telephone to **(866) 365-8204**. You must provide the information listed in the bullet points above and a statement that you are requesting an expedited review. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file. Please note that your request

for review will only be expedited if the Part D drug has not already been furnished and the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at <http://www.hhs.gov/dab/>. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll free) if you have questions about filing an appeal.

cc:

Shannon Fisher
Novocure
195 Commerce Way
Portsmouth, NH 03801

Excellus Health Plan, Inc.
Attn: Shea Kolar
PO Box 4717
Syracuse, NY 13221

Appeals Work Station
Maximus Federal Services
Medicare Part C QIC
3750 Monroe Ave., Suite 702
Pittsford, NY 14534-1302

Enclosures:

OMHA-152, Decision
DAB-101, Request for Review

REQUEST FOR REVIEW OF ADMINISTRATIVE LAW JUDGE (ALJ) MEDICARE DECISION / DISMISSAL

1. APPELLANT (the party requesting review)

2. ALJ APPEAL NUMBER (on the decision or dismissal)

3. BENEFICIARY*

4. HEALTH INSURANCE CLAIM NUMBER (HICN)*

*If the request involves multiple claims or multiple beneficiaries, attach a list of beneficiaries, HICNs, or other information to identify all claims being appealed.

5. PROVIDER, PRACTITIONER, OR SUPPLIER

6. SPECIFIC ITEM(S) OR SERVICE(S)

7. Medicare claim type: ☐ Part A ☐ Part B ☐ Part C - Medicare Advantage
☐ Part D - Medicare Prescription Drug Plan ☐ Entitlement/enrollment for Part A or Part B

8. Does this request involve authorization for an item or service that has not yet been furnished?

☐ Yes If Yes, skip to Block 8.
☐ No If No, Specific Dates of Service:

9. If the request involves authorization for a prescription drug under Medicare Part D, would application of the standard appellate timeframe seriously jeopardize the beneficiary's life, health, or ability to regain maximum function (as documented by a physician) such that expedited review is appropriate? ☐ Yes ☐ No

I request that the Medicare Appeals Council review the ALJ's ☐ decision or ☐ dismissal order [check one] dated _____. I disagree with the ALJ's action because (specify the parts of the ALJ's decision or dismissal you disagree with and why you think the ALJ was wrong):

(Attach additional sheets if you need more space)

PLEASE ATTACH A COPY OF THE ALJ DECISION OR DISMISSAL ORDER YOU ARE APPEALING.

DATE			DATE		
APPELLANT'S SIGNATURE (the party requesting review)			REPRESENTATIVE'S SIGNATURE (include signed appointment if not already submitted.)		
PRINT NAME			PRINT NAME		
ADDRESS			ADDRESS		
CITY, STATE, ZIP CODE			CITY, STATE, ZIP CODE		
TELEPHONE NUMBER	FAX NUMBER	E-MAIL	TELEPHONE NUMBER	FAX NUMBER	E-MAIL

(SEE FURTHER INSTRUCTIONS ON PAGE 2)

If you have additional evidence, submit it with this request for review. If you need more time, you must request an extension of time in writing now, explaining why you are unable to submit the evidence or legal argument now.

If you are a provider, supplier, or a beneficiary represented by a provider or supplier, and your case was reconsidered by a Qualified Independent Contractor (QIC), the Medicare Appeals Council will not consider new evidence related to issues the QIC has already considered unless you show that you have a good reason for submitting it for the first time to the Medicare Appeals Council.

IMPORTANT: Include the HICN and ALJ Appeal Number on any letter or other material you submit.

This request must be received within 60 calendar days after you receive the ALJ's decision or dismissal, unless we extend the time limit for good cause. We assume you received the decision or dismissal 5 calendar days after it was issued, unless you show you received it later. If this request will not be received within 65 calendar days from the date on the decision or dismissal order, please explain why on a separate sheet.

You must file your request for review in writing with the Medicare Appeals Council at:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

You may send the request for review by U.S. Mail, a common carrier such as FedEx, or by fax to (202) 565-0227. If you send a fax, please do not also mail a copy. **You must send a copy of your appeal to the other parties and indicate that all parties, to include all beneficiaries, have been copied on the request for review. For claims involving multiple beneficiaries, you may submit a copy of the cover letters issued or a spreadsheet of the beneficiaries and addresses who received a copy of the request for review.**

If you have any questions about your request for review or wish to request expedited review of a claim involving authorization of your prescription drug under Medicare Part D, you may call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100. You may also visit our web site at www.hhs.gov/dab for additional information on how to file your request for review.

PRIVACY ACT STATEMENT

The collection of information on this form is authorized by the Social Security Act (section 205(a) of title II, section 702 of title VII, section 1155 of Title XI, and sections 1852(g)(5), 1869(b)(1), 1871, 1872, and 1876(c)(5)(B) of title XVIII, as appropriate). The information provided will be used to further document your claim. Information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your claim. Information you furnish on this form may be disclosed by the Department of Health and Human Services or the Social Security Administration to another person or governmental agency only with respect to programs under the Social Security Act and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services, the Social Security Administration, or other agencies.



**Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, MO**

Appeal of:	ALJ Appeal No.: 1-5309926775
Beneficiary:	Medicare: Part C
HICN:	Before: Kimberley Woodyard Administrative Law Judge

DECISION

Upon a *de novo* review of the record in this case, and following hearing, this Administrative Law Judge enters a **FAVORABLE** decision for . Humana Insurance Company shall pre-approve tumor treatment field therapy for

Procedural History

This appeal is before this Administrative Law Judge following prior adverse decisions of the Plan and Quality Improvement Organization, both of which denied approval of the proposed treatment. The reconsideration decision was issued on October 28, 2016, after which the Appellant filed a request for hearing before an Administrative Law Judge, on November 2, 2016.

Inasmuch as the request was timely and the amount in controversy meets the jurisdictional requirements for an ALJ hearing, 42 C.F.R. §§ 422.600, 422.602, this ALJ has jurisdiction to conduct the *de novo* review, 42 C.F.R. § 405.1000(d), and issue a decision.

Hearing on this matter was held on December 29, 2016, at which Jorge Morales, the Beneficiary's representative appeared. Humana appeared by Dr. Bruce Neibylski. Exhibits 1-4 were admitted into evidence without objection. Upon conclusion of argument and testimony, the record was closed and the hearing was concluded.

Issue

This issue is whether all plan contract coverage requirements have been met warranting payment under Title XVIII of the Social Security Act.

Findings of Fact

This Judge finds the following facts to be established by the evidence in the record:

1. _____ is a sixty-eight year-old man suffering from glioblastoma of the right temporal lobe. (Exh. 3, p. 3). This is a particularly aggressive malignant primary brain tumor, (Exh. 3, p. 21), with which he was diagnosed on April 8, 2015, (Exh. 3, p. 3).
2. On August 31, 2016, Dr. _____ signed a prescription for _____ to receive six months of Optune -- treatment to start ASAP. (Exh. 3, p. 1).
3. _____ had already undergone, among other treatments, six months of radiation with concurrent temozolomide. (Exh. 3, p. 3). He continued, however, to have seizures and staring spells. (Exh. 3, p. 4). His symptoms had gotten worse since his last appointment, but were still better than several months prior, following the radiation. *Id.* _____ is also inflicted with diabetes and hypertension. *Id.* At his doctor visit of August 31, 2016, the heterogeneous mass in his right anterior temporal lobe that had minimally increased. *Id.* at 8. The tumor was progressive. *Id.* In light of the clinical and radiographic continued progression of the disease, Dr. Randazzo recommended that _____ initiate the use of Optune, and she began the paperwork for him. *Id.* The documentation of the continued progression is also supported by the physician notes of the prior encounter of August 3, 2016. (Exh. 3, pp. 11-16).
4. Optune uses low-intensity electric fields to help slow or stop glioblastoma cancer cells from dividing. *See* <https://www.optune.com/therapy/how-therapy-works>. Four adhesive patches, or transducer arrays, are applied to the scalp and connected to the device and a battery to deliver the therapy. *Id.*
5. Optune, previously called NovoTTF-100A System, received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011.¹
6. On October 5, 2015, the Provider received premarket approval from the FDA for use of Optune in patients newly diagnosed with glioblastoma.² The FDA approval was based upon the premarket approval process, not the abbreviated 510(k) clearance process.
7. On December 15, 2015, the Journal of the American Medical Association ("JAMA") published an article analyzing the results of a phase III clinical trial related to TTFT. Stupp, Roger, M.D. et al., *Maintenance Therapy With Tumor-Treating Field Plus Temozolomide vs Temozolomide Alone for Glioblastoma A Randomized Clinical Trial*, 314 JAMA 2535 (2015); (Exh. 3, pp. 22, et seq.). The analysis of the clinical trial showed that adding TTFT to maintenance temozolomide in a population with new onset glioblastoma "significantly prolonged progression-free and overall survival."
8. In an article published in July 2015 in *Current Treatment Options in Oncology*, results of a phase III clinical trial for recurrent glioblastoma were discussed, as well as interim

¹ http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100034a.pdf.

² http://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034S013a.pdf.

results in a study involving patients newly diagnosed with glioblastoma. *See* 16 Curr. Treat. Options in Oncol. 40 (2015); (Exh. 3, pp. 57 *et seq.*). This article reported that TTFT was “shown to have equivalent efficacy when compared to the best physician’s choice chemotherapy in a registration phase III clinical trial for recurrent glioblastoma.” *Id.* The results of this clinical trial then led to FDA approval for the device. *Id.* Interim results of a later clinical trial for newly diagnosed patients showed significant improvement in outcomes of the patients, leading to crossover of trial subjects from the control group to the experimental group. *Id.*

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with the decisions of the Medicare contractor and the Qualified Independent Contractor is entitled to a hearing before the Secretary of the Department of Health and Human Services, Social Security Act § 1869(b)(1)(A), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner, 42 C.F.R. § 422.602. The request for hearing is timely if filed within sixty days of the reconsideration determination. *Id.* The minimum amount in controversy required for hearing before an Administrative Law Judge are published in the Federal Register. In this instance, this ALJ uses the projected value of the services to compute the amount in controversy. 42 C.F.R. § 422.600(c).

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the Appellant’s favor. 42 C.F.R. § 405.1032(a).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue and makes a decision based on the hearing record. 42 C.F.R. § 405.1000(d).

II. Principles of Law

A. The Statutes and Regulations

Sections 1812 and 1813 of the Act establish the scope of benefits of the hospital insurance program under Medicare Part A. Section 1814 establishes conditions for, and limitations on, payment for services furnished by providers. Medicare coverage for hospitalization includes payment for the services generally available in a hospital: bed and board, nursing services and other related services, use of hospital facilities, medical social services, drugs, supplies and equipment, diagnostic or therapeutic items or services, and medical or surgical services provided by certain interns and residents pursuant to section 1861(b) of the Act. In addition, section 1861 defines hospitals to include institutions which provide “therapeutic services for medical diagnosis, treatment and care of injured, disabled, or sick persons, or rehabilitation or injured, disabled or sick persons.” Section 1862(a)(1)(A), prohibits Medicare

payments for anything which is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

In the event the services are found to be “not medically reasonable and necessary” or “custodial in nature” under section 1862(a)(1) or (a)(9) of the Act, section 1879 provides for limitation on liability for Medicare payments. If the beneficiary had no knowledge that the services would not be covered, but the provider of the services did, then the provider is liable and cannot seek or retain payment by the beneficiary. The regulations at 42 C.F.R. § 411.400 *et seq.* and HCFA Ruling 95-1 address how to determine if the beneficiary or provider/supplier had the requisite degree of knowledge to make them liable under section 1879. *See also* CMS, Medicare Claims Processing Manual (MCPM), Internet-Only Manual Pub. 100-4, Ch. 30, § 20. In general, the existence of a notice, manual, or community medical standard is sufficient to constitute notice as applicable to the provider. 42 C.F.R. § 411.406.

An MA plan must provide an enrollee with coverage for all items and services covered by Medicare Part A (except hospice services) and Part B that are available to beneficiaries in the plan's service area. *See* Section 1852 (a) (1) of the Social Security Act (Act); 42 C. F. R. §§ 422.100 (c) (1); 422.101 (a). An MA plan must comply with National Coverage Determinations (NCDs), general coverage guidelines included in original Medicare manuals and instructions, and written coverage decisions of local Medicare contractors with jurisdiction over claims in the geographic area in which services are covered under the MA plan. 42 C.F.R. § 422.101(b). Therefore, if Medicare does not cover an item or service, unless the plan covers the item or service through supplemental benefits, the Plan is not required cover the item or service at issue. *See* 42 C.F.R. § 422.102.

B. Policy and Guidance

The Social Security Act vests in the Secretary the authority to make coverage decisions. Under that authority, CMS issues National Coverage Determinations (NCDs) that state whether specific medical items, services, treatment procedures, or technologies may be paid for by Medicare. In the absence of a specific NCD, the Medicare contractor is responsible for determining whether an item or service is reasonable and necessary. (See preface to Coverage Issues Manual (reprinted at 54 Fed. Reg. 34555 (Aug. 21, 1989)). Accordingly, in addition to looking to the binding statutory and regulatory authority, this ALJ must accord substantial deference to manuals, program memoranda and other issuances issued by the Center for Medicare and Medicaid Services (CMS) and its carriers and intermediaries. 42 C.F.R. § 405.1062. Moreover, an ALJ may not set aside or review the validity of a local coverage policy in the context of a claim appeal. 42 C.F.R. § 405.1062(c). Thus, the ALJ looks to the Local Coverage Determinations (LCD), if any, and the Medicare Benefit Policy Manual.

In this instance, there is an LCD, to wit Tumor Treatment Field Therapy (TTFT)(L34823). With regard to medical necessity, it provides in full:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this local coverage determination, the criteria for “reasonable and necessary,” based

on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

For an item to be covered by Medicare, a detailed written order (DWO) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed DWO, the item will be denied as not reasonable and necessary.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

LCD 34823 (Effective July 1, 2016).³ The language in the LCD prior to this effective date is identical. LCD 34823 (effective 10/01/2015 – 7/01/2016).

Historically, in making coverage determinations, CMS has interpreted the terms "reasonable and necessary" to mean that the item or service in question is safe and effective and not experimental. CMS has further determined that the relevant tests for applying these terms are whether the item or service has been proven safe and effective based on authoritative evidence, or alternatively, whether the item or service is generally accepted in the medical community as safe and effective for the condition for which it is used. 54 Fed. Reg. 4304 (Jan. 30, 1989); 60 Fed. Reg. 48417 (Sept. 19, 1995); see also 52 Fed. Reg. 15,560 (Apr. 29, 1987). Indeed, CMS has provided guidance in the *Medicare Program Integrity Manual* (CMS Pub. 100-08) (*MPIM*) to assist contractors in developing LCDs to aid in creating relevant tests and guidance. The *MPIM* contemplates that, in making a determination as to whether an item or service is reasonable and necessary, contractors will analyze whether the item or service is safe and effective, and not experimental or investigational. *MPIM*, Ch. 13 at § 13.5.1. Contractors shall consider a service reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational; and
- Appropriate, including the duration and frequency that is considered appropriate for the service.

The *MPIM* further instructs contractors to base LCDs on the strongest evidence available at the time the determination is issued. In order of preference, this includes:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and ALJs and the Medicare Appeals Council are not bound by CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. 42 C.F.R. § 405.1062(a).

- General acceptance by the medical community (standards of practice), supported by sound medical evidence based on:

- o Scientific data or research studies published in peer-reviewed medical journals;
- o Consensus of expert medical opinion (i.e., recognized authorities in the field);

or

³ Mr. Chason made his authorization request on September 6, 2016. (Exh. 2, p. 23).

o Medical opinion derived from consultations with medical associations or other health care experts.

Id. at § 13.7.1. The Manual further explains:

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

Id.

C. The Terms of the Plan (Evidence of Coverage)

The insurance plan that governs this proceeding is located in Exhibit 1 and provides that it covers services in accord with Medicare rules. (Exh. 1, p. 53). The services “*must* be medically necessary,” which means that the services are “needed for the prevention, diagnosis, or treatment of your medical condition and meet accepted standards of medical practice.” (Exh. 1, p. 35)(emphasis in original). The plan charts what services are not covered, including, “Services considered not reasonable and necessary, according to the standards of Original Medicare.” (Exh. 1, p. 87). Another exclusion is: “Experimental medical and surgical procedures, equipment and medications. Experimental procedures and items are those items and procedures determined by our plan and Original Medicare to not be generally accepted by the medical community.” *Id.*

Analysis

seeks a decision requiring Humana Insurance Company) to pre-approve tumor treatment field therapy, asserting that the services are not experimental for his diagnosis. The Plan argued that the relevant Local Coverage Determination stated that Tumor Treatment Field Therapy was not covered by Medicare as not medically reasonable and necessary treatment. The MA Plan is bound to follow Local Coverage Determinations.

has a brain tumor that has failed other treatment and, accordingly, seeks treatment – Tumor Treatment Field Therapy. He has been through radiation and other treatment and yet his disease is progressing. Medicare, through its contractor, has issued a policy statement to which this ALJ, in the first instance, is required to accord “substantial deference.” In order to deviate from that guidance, the specific LCD applicable to this case, I must have a cogent explanation for disregarding that guidance. *See* 42 C.F.R. § 405.1062. In this instance, the grounds for disregarding the LCD are copious and warranted. The therapy has been shown to be safe and effective for use in patients with recurrent glioblastoma (after other treatments have been tried without sufficient success, all as here) and it is medically reasonable and necessary to treat Mr. brain condition.

The relevant LCD states that tumor treatment field therapy will be denied as not reasonable and necessary. However, the Information and Basis of Decision section of the applicable version LCD showed that the most recent literature reviewed for purposes of the LCD’s formation was published in 2013. If additional or more recent literature was reviewed, it is not listed in the LCD. LCD L34823. In any event, the advancement of medicine and science

can sometimes outpace the current or relevant version of an LCD. In this case, the advancement is obvious. Indeed, subsequently reported data from the FDA, phase III clinical trials, and NCCN guidelines is available to this ALJ for review and analysis, and shows the LCD may be behind the medical literature curve as applied to this patient.

The Optune device received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011. On October 5, 2015, the FDA gave premarket approval for use of Optune in patients with newly diagnosed glioblastoma. The FDA website explains that premarket approval (“PMA”) entails the following:

PMA is the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).⁴

While FDA premarket approval does not establish that the device is medically reasonable and necessary pursuant to Medicare requirements, it does ensure that the FDA has closely examined the device and its application. In this case, the FDA determined that sufficient scientific evidence existed to provide the FDA with assurance that the device was safe and effective for its intended use both in patients with recurrent and newly diagnosed glioblastoma. From this perspective, the use of the device meets Medicare guidance requiring that a device be proven safe and effective based on authoritative evidence.

The FDA approval also helps shows that the device is safe, and not experimental or investigational. Medicare does not pay for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. Social Security Act § 1862(a)(1). To be reasonable and necessary, the procedure must be safe and effective and not experimental.⁵

Second, this ALJ has reviewed clinical studies in the record related to the use of the Optune device. Results from a phase III clinical trial utilizing TTFT in patients with recurrent glioblastoma was shown to have equivalent efficacy when compared to the best physician’s choice for chemotherapy. With respect to patients newly diagnosed with glioblastoma, results of a phase III study released in a December 15, 2015, JAMA article showed that adding TTFT to maintenance temozolomide significantly prolonged progression-free and overall survival. *Id.* Significantly, patients in the control group in the JAMA-reported study crossed over to the combined therapy group for TTFT treatment due to the improvement in outcomes seen. *Id.* The results from these phase III trials also led to FDA approval for the Optune device. *Id.* Again, these trials showed that the Optune device was safe, non-investigational and effective. In

⁴<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm>.

⁵ This ALJ is mindful of the distinction between FDA approval and Medicare’s “reasonable and necessary” criteria. The FDA concentrates on the safety of a device or procedure, whereas Medicare reviews whether the procedure meets the broader requirement, “reasonable and necessary.” These entities make determinations under different statutory standards as well as different delegated authority. *See generally* 68 Fed. Reg. 55,636, 54 Fed. Reg. 4307. FDA approval does not generally entitle a procedure to coverage. 68 Fed. Reg. 55,636.

addition, these trials showed that the Optune device was appropriate for [REDACTED]; individual needs, specifically the treatment of recurrent glioblastoma.

Third, the use of TTFT is generally accepted by the medical community. In the 2015 version of the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology Central Nervous System Cancers guidelines, alternating electric field therapy is a treatment option suggested for glioblastoma. This suggestion was found in a treatment guideline from a national cancer organization, not evidence based on an individual physician treating a single patient in a clinical setting. As such, this ALJ finds that TTFT treatment is generally accepted in the medical community as safe and effective for the treatment of recurrent glioblastoma.

Overall, a review of the literature available demonstrates that the Optune device received FDA premarket approval, and that it is safe and effective and not investigational/experimental. The use of the Optune device in a population with recurrent glioblastoma was proven effective and appropriate through a phase III clinical trial; and the use of the Optune device appears in national cancer treatment guidelines for treatment of glioblastoma, showing general acceptance by the medical community. A number of commercial health plans also now cover TTFT.

The final aspect is the medical record of [REDACTED], whose disease, without this treatment, will likely progress to cause an earlier death than need be the case. A review of the medical records and hearing demonstrated that [REDACTED] has already undergone extensive treatment for the cancer and there appear to be no further options; the disease is progressing despite the treatments. [REDACTED] has no alternative care available to halt the progression of the disease. The preponderance of the evidence is that TTFT therapy is warranted to battle the progression of disease and prolong his life.

Conclusions of Law

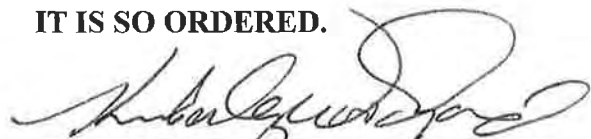
[REDACTED] insurance benefits are determined by the terms of his Medicare Advantage PPO plan with a Medicare contract. Under the terms of the plan, Medicare rules and coverage determinations guide whether an item or device will be covered. In order for coverage to exist, a procedure must be medically reasonable and necessary. Optune (TTFT) has been shown to be safe and effective and is medically reasonable and necessary for the treatment of Mr. [REDACTED] condition. Plan coverage is warranted.

Order

The Medicare Contractor is DIRECTED to process the request for pre-approval of the treatment in accord with this decision.

IT IS SO ORDERED.

Dated: JAN 9 2016



Kimberley Woodyard
U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, Missouri

Appeal of:	ALJ Appeal No.: 1-7867023070
Beneficiary:	Medicare Part: B
DOS: 09/28/2017 10/28/2017 11/28/2017	
HICN:	Before: Kimberley Woodyard U.S. Administrative Law Judge

DECISION

Upon a *de novo* review of the record and, following hearing, this Administrative Law Judge enters a **FULLY FAVORABLE** decision for the Appellant is entitled to coverage for Tumor Treatment Field Therapy.

**FINDINGS OF FACT AND
HISTORY OF THE CASE**

sixty-five years old at the time, suffered from glioblastoma multiforme, diagnosed in June 2017. (Exh. 2, pp. 3, 19). A tumor resection was not thought feasible. (Exh. 2, p. 14). was explained his treatment options, and chose to undergo standard of care chemo-radiation, followed by adjuvant Temodar and Optune.¹ (Exh. 2, pp. 7, 13). On June 16, 2017, physician signed an Optune Prescription Form prescribing Optune treatment for to start the week of September 18, 2017, for six months. (Exh. 2, p. 1). The record includes invoices for Optune for September 28, 2017, October 28, 2017, and November 28, 2017. (Exh. 2, pp. 42-44). A medication list dated June 17, 2017, shows that temozolomide (Temodar) was part of medication regimen. (Exh. 2, p. 26).

Optune treats cancer by using tumor-treating fields (TTF) to interfere with the division of malignant cells. It is locally or regionally delivered, using alternating electric fields to disrupt the

¹ The record does not include documentation that shows radiation and adjuvant Temodar regimen. (See Exh. 2).

response to the standard of care chemo-

rapid cell division exhibited by cancer cells. (Exh. 3, p. 7). Optune with temozalomid is indicated for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy. (Exh. 3, p. 18). It is intended as an alternative to standard medical therapy for glioblastoma multiforme after surgical and radiation options have been exhausted. *Id.* Optune received pre-market approval from the FDA for treatment of glioblastoma in April 2011,² based upon the result of a large randomized, controlled trial of patients with recurrent GBM. *Id.* The overall survival and progression-free survival to chemotherapy with minimal toxicity and an improvement in patients quality of life, is demonstrated, compared to that of chemotherapy. *Id.* Subsequently, in 2015, the FDA approved Optune for newly diagnosed glioblastoma in combination with temozolomide.³ The trials showed superior efficacy in both progression-free survival as well as overall survival. *Id.*

On December 15, 2015, the Journal of the American Medical Association (JAMA) published an article analyzing the results of a phase III clinical trial related to TTFT.⁴ (Exh. 3, p. 5, *et. seq.*). The analysis of the clinical trial showed that adding TTFT to maintenance temozolomide in a population with new onset glioblastoma “significantly prolonged progression-free and overall survival.” (Exh. 3, p. 13). After conclusion of the study, patients in the control group with ongoing maintenance therapy were offered TTFT therapy. (Exh. 3, p. 9).

The Medicare Administrative Contractor, initially and on redetermination, denied the claim for the services. The Qualified Independent Contractor (QIC) denied reconsideration of the claim on August 13, 2018. The QIC found that based on the available documentation, Medicare requirements were not met. filed a request for hearing before an Administrative Law Judge (ALJ) on September 10, 2018. Since the request was timely and the amount in controversy met the jurisdictional requirements for an ALJ hearing, 42 C.F.R. §§ 405.1002(a)(1), 405.1006(b)(1), this ALJ has jurisdiction to conduct the *de novo* review and issue a decision. 42 C.F.R. § 405.1000(d).

Hearing on this matter was held on November 19, 2018, at which Debra Parrish, Esq., appeared on behalf of Julie Miles and Tim Parks, both RNs and Clinical Appeals Specialists with Novocure, also appeared. Exhibits 1-3 were admitted into the record without objection. Following presentation of the case, the record was closed and the hearing concluded.

The issues before the ALJ include all the issues brought out in the initial determination, coverage determination, or organization determination; redetermination; or reconsideration that were not decided entirely in the Appellant’s favor, for the claims or other appealed matters specified in the request for hearing. The issue was whether all Medicare coverage requirements have been met warranting payment for the Tumor Treatment Field Therapy.

² http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100034a.pdf.

³ http://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034S013a.pdf.

⁴ Stupp, Roger, M.D. et al., *Maintenance Therapy With Tumor-Treating Field Plus Temozolomide vs Temozolomide Alone for Glioblastoma A Randomized Clinical Trial*, 314 JAMA 2535 (2015).

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with the decisions of the Medicare contractor and the Qualified Independent Contractor is entitled to a hearing before the Secretary of the Department of Health and Human Services, Social Security Act § 1869(b)(1)(A), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner, 42 C.F.R. § 405.1002. The request for hearing is timely if filed within sixty days after receipt of a Qualified Independent Contractor decision. 42 C.F.R. § 405.1014(c). The minimum amount in controversy required for hearing before an Administrative Law Judge are published in the Federal Register.

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the Appellant's favor. 42 C.F.R. § 405.1032(a).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue and makes a decision based on the hearing record. 42 C.F.R. § 405.1000(d).

II. Principles of Law

A. Statutes and Regulations

Medicare Part B provides coverage to eligible beneficiaries for all or part of the cost of "medical and other health services," a term that is defined by the Social Security Act as including, among many other things, durable medical equipment. *See* Social Security Act § 1832(a)(1)(B); 42 C.F.R. § 410.10(h). Notwithstanding any other provision of Title XVIII of the Social Security Act, no payment may be made under parts A or B for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Social Security Act § 1862(a)(1)(A). Similarly, Medicare precludes payment to any claimant unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." Social Security Act § 1833(e).

B. Policy and Guidance

The Social Security Act vests in the Secretary the authority to make coverage decisions. Under that authority, CMS issues National Coverage Determinations (NCDs) that state whether specific medical items, services, treatment procedures, or technologies may be paid for by

Medicare. In the absence of a specific NCD, the Medicare contractor is responsible for determining whether an item or service is reasonable and necessary. (See preface to Coverage Issues Manual (reprinted at 54 Fed. Reg. 34555 (Aug. 21, 1989))). Accordingly, in addition to looking to the binding statutory and regulatory authority, this ALJ must accord substantial deference to manuals, program memoranda and other issuances issued by the Center for Medicare and Medicaid Services (CMS) and its carriers and intermediaries. 42 C.F.R. § 405.1062. Thus, the ALJ looks to the Local Coverage Determinations (LCD), if any, and the Medicare Benefit Policy Manual.

Historically, in making coverage determinations, CMS has interpreted the terms "reasonable and necessary" to mean that the item or service in question is safe and effective and not experimental. CMS has further determined that the relevant tests for applying these terms are whether the item or service has been proven safe and effective based on authoritative evidence, or alternatively, whether the item or service is generally accepted in the medical community as safe and effective for the condition for which it is used. 54 Fed. Reg. 4304 (Jan. 30, 1989); 60 Fed. Reg. 48417 (Sept. 19, 1995); see also 52 Fed. Reg. 15,560 (Apr. 29, 1987). Indeed, CMS has provided guidance in the *Medicare Program Integrity Manual* (CMS Pub. 100-08) (*MPIM*) to assist contractors in developing LCDs to aid in creating relevant tests and guidance. The *MPIM* contemplates that, in making a determination as to whether an item or service is reasonable and necessary, contractors will analyze whether the item or service is safe and effective, and not experimental or investigational. *MPIM*, Ch. 13 at § 13.5.1. Contractors shall consider a service reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational; and
- Appropriate, including the duration and frequency that is considered appropriate for the service.

The *MPIM* further instructs contractors to base LCDs on the strongest evidence available at the time the determination is issued. In order of preference, this includes:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and ALJs and the Medicare Appeals Council are not bound by CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. 42 C.F.R. § 405.1062(a).

- General acceptance by the medical community (standards of practice), supported by sound medical evidence based on:

- o Scientific data or research studies published in peer-reviewed medical journals;
- o Consensus of expert medical opinion (i.e., recognized authorities in the field);
- or
- o Medical opinion derived from consultations with medical associations or other health care experts.

Id. at § 13.7.1. The Manual further explains:

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

Id.

There is a Local Coverage Determination stating CMS' guidance for Tumor Treatment Field Therapy: CGS Administrators, LLC, Local Coverage Determination, LCD L34823, Tumor Treatment Field Therapy (TTFT) (January 2017). This LCD provides, without elucidation, that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.⁵ The related Policy Article states that tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit and must meet the reasonable and necessary requirements set out in the related LCD to be eligible for reimbursement. CGS Administrators, LLC, Local Coverage Article for Tumor Treatment Field Therapy Article A52711 (Article A52711) (January 2017).

Analysis

The issue is whether the Appellant's services are entitled to coverage. Pursuant to section 405.1032(a) of the regulations (42 C.F.R.), the unfavorable findings of the contractors are the issues before this ALJ. The QIC found that based on the available documentation, Medicare requirements outlined in the LCD, NCD, and Medicare manuals were not met.

There is no NCD specific to tumor treatment field therapy. This ALJ, therefore, looks to the relevant LCD for guidance. ALJs are not bound by LCDs and will give substantial deference to the policies if they are applicable to a particular case. 42 C.F.R. § 405.1062. If an ALJ declines to follow an LCD in a particular case, the ALJ must explain the reasons why the policy was not followed. *Id.*

In this case, this ALJ declines to follow LCD L34823 for multiple reasons. The therapy has been shown to be safe and effective for use in patients with recurrent glioblastoma (after chemotherapy, radiation and/or surgery has been tried without sufficient success)⁶, and it is medically reasonable and necessary to treat _____ condition.

⁵ This latest version of the LCD, omits entirely the literature previously shown in the 2016 LCD (an update from the 2015 version, which is not markedly distinguishable).

⁶ It was determined that surgery was not feasible for _____ No medical documentation was submitted that showed _____ response to standard care chemo-radiation therapy and temozolomide. However, since he continued with TTF therapy after conventional treatment, it is reasonable to assume that conventional treatment was not sufficiently successful.

The relevant LCD states that tumor treatment field therapy will be denied as not reasonable and necessary. This version of the LCD omits entirely the literature previously shown in the prior LCDs. In any event, the advancement of medicine and science can sometimes outpace the current or relevant version of an LCD. Subsequently reported data from the FDA, phase III clinical trials, and NCCN guidelines is available to this ALJ for review and analysis, and shows the LCD, at best, is behind the medical literature curve – at least as applied to this patient. The more helpful and relevant Medicare guidance in this instance is the *Medicare Program Integrity Manual* (CMS Pub. 100-08) (*MPIM*), which provides the more appropriate and helpful guidance for making a determination as to whether an item or service is reasonable and necessary, and not experimental or investigational. *MPIM*, Ch. 13 at § 13.5.1.

Applying that guidance, this ALJ first finds that the Optune device received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011. On October 5, 2015, the FDA gave premarket approval for use of Optune in patients with newly diagnosed glioblastoma. The FDA website explains that premarket approval (PMA) entails the following:

PMA is the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).⁷

While FDA premarket approval does not establish that the device is medically reasonable and necessary pursuant to Medicare requirements, it does ensure that the FDA has closely examined the device and its application. In this case, the FDA determined that sufficient scientific evidence existed to provide the FDA with assurance that the device was safe and effective for its intended use both in patients with recurrent and newly diagnosed glioblastoma. From this perspective, the use of the device meets Medicare guidance requiring that a device be proven safe and effective based on authoritative evidence.

The FDA approval, along with the other evidence below, also helps shows that the device is safe, and not experimental or investigational. Medicare does not pay for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. Social Security Act § 1862(a)(1). To be reasonable and necessary, the procedure must be safe and effective and not experimental.

Second, this ALJ has reviewed clinical studies in the record related to the use of the Optune device. Results from a phase III clinical trial utilizing TTFT in patients with recurrent glioblastoma was shown to have equivalent efficacy when compared to the best physician's choice for chemotherapy. With respect to patients newly diagnosed with glioblastoma, results of a phase III study released in a December 15, 2015, JAMA article showed that adding TTFT to maintenance temozolomide significantly prolonged progression-free and overall survival. Significantly, patients in the control group in the JAMA-reported study crossed over to the

⁷<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm>

combined therapy group for TTFT treatment due to the improvement in outcomes seen. The results from these phase III trials also led to FDA approval for the Optune device. Again, these trials showed that the Optune device was safe, non-investigational and effective. It is noteworthy that the 2015 study contains proof of efficacy. In contrast, the LCD lacks any substantive guidance, analysis, or even recent citation to medical authority. In addition, these trials showed that the Optune device was appropriate for needs, specifically the treatment of recurrent glioblastoma.

Third, the use of TTFT is generally accepted by the medical community. In the 2015 version of the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology Central Nervous System Cancers guidelines, alternating electric field therapy is a treatment option suggested for glioblastoma. This suggestion was found in a treatment guideline from a national cancer organization, not evidence based on an individual physician treating a single patient in a clinical setting. As such, TTFT treatment is generally accepted in the medical community as safe and effective for the treatment of recurrent glioblastoma.

Overall, a review of the literature available showed that the Optune device received FDA premarket approval, showing that it was safe and effective and not investigational/experimental. The use of the Optune device in a population with recurrent glioblastoma was proven effective and appropriate through a phase III clinical trial; and the use of the Optune device appears in national cancer treatment guidelines for treatment of glioblastoma, showing general acceptance by the medical community. A number of commercial health plans also now cover TTFT.

For the reasons stated above, this ALJ finds that Optune (TTFT) has been shown to be safe and effective, and is not experimental. Medicare coverage is thus available for tumor treatment field therapy.

Conclusions of Law

Medicare coverage exists for the Optune Tumor Treatment Field Therapy services (E0766) provided to the Beneficiary for dates of service September 28, 2017, October 28, 2017, and November 28, 2017.

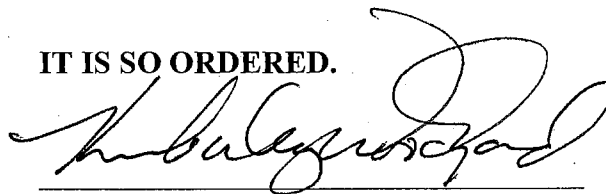
Order

The Medicare Contractor shall process the claim in accord with this decision.

IT IS SO ORDERED.

NOV 20 2018

Dated: _____



Kimberley Woodyard

U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, Missouri

Appeal of:

ALJ Appeal No.: 1-78556544287

Beneficiary:

Medicare Part: B

DOS: 09/15/2017
10/15/2017
11/15/2017

HICN:

Before: Kimberley Woodyard
U.S. Administrative Law Judge

DECISION

Upon a *de novo* review of the record and, following hearing, this Administrative Law Judge enters a **FULLY FAVORABLE** decision for the Appellant is entitled to coverage for Tumor Treatment Field Therapy.

**FINDINGS OF FACT AND
HISTORY OF THE CASE**

sixty-five years old at the time, suffered from a glioblastomas of the right frontal region. (Exh. 2, p. 10). He was newly diagnosed with this cancer in 2015. He underwent surgery on November 11, 2015. *Id.* He completed radiation and daily chemotherapy on February 19, 2016, followed by six cycles of adjuvant temozolomide, which he completed in August 2016.¹ *Id.* At a physician visit on July 12, 2017, the oncologist noted that had good compliance with the Optune device, infrequently had minimal skin irritation from the Optune pads, was seizure free, and continued to do well. (Exh. 2, pp. 10, 12). An MRI on that date showed stable postsurgical changes of the right frontal craniotomy and right frontal lobe resection cavity, without findings to suggest recurrence. (Exh. 2, p. 13). On July 20, 2017, Mr. physician signed an existing patient Optune Prescription Form prescribing Optune

¹ The record does not include documentation that shows Mr. adjuvant temozolomide regimen. (See Exh. 2).

response to the radiation, chemotherapy, and

treatment for Mr. [REDACTED] for six months.² (Exh. 2, p. 1). The record includes invoices for Optune for September 15, 2017, October 15, 2017, and November 15, 2017. (Exh. 2, pp. 7-9).

Optune treats cancer by using tumor-treating fields (TTF) to interfere with the division of malignant cells. It is locally or regionally delivered, using alternating electric fields to disrupt the rapid cell division exhibited by cancer cells. (Exh. 3, p. 7). Optune with temozolomide is indicated for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy. (Exh. 3, p. 18). It is intended as an alternative to standard medical therapy for glioblastoma multiforme after surgical and radiation options have been exhausted. *Id.* Optune received pre-market approval from the FDA for treatment of glioblastoma in April 2011,³ based upon the result of a large randomized, controlled trial of patients with recurrent GBM. *Id.* The overall survival and progression-free survival to chemotherapy with minimal toxicity and an improvement in patients quality of life, is demonstrated, compared to that of chemotherapy. *Id.* Subsequently, in 2015, the FDA approved Optune for newly diagnosed glioblastoma in combination with temozolomide.⁴ The trials showed superior efficacy in both progression-free survival as well as overall survival. *Id.*

On December 15, 2015, the Journal of the American Medical Association (JAMA) published an article analyzing the results of a phase III clinical trial related to TTFT.⁵ (Exh. 3, p. 5, *et. seq.*). The analysis of the clinical trial showed that adding TTFT to maintenance temozolomide in a population with new onset glioblastoma “significantly prolonged progression-free and overall survival.” (Exh. 3, p. 13). After conclusion of the study, patients in the control group with ongoing maintenance therapy were offered TTFT therapy. (Exh. 3, p. 9).

The Medicare Administrative Contractor, initially and on redetermination, denied the claim for the services. The Qualified Independent Contractor (QIC) denied reconsideration of the claim on August 13, 2018. The QIC found that based on the available documentation, Medicare requirements were not met. Mr. Meyers filed a request for hearing before an Administrative Law Judge (ALJ) on September 6, 2018. Since the request was timely and the amount in controversy met the jurisdictional requirements for an ALJ hearing, 42 C.F.R. §§ 405.1002(a)(1), 405.1006(b)(1), this ALJ has jurisdiction to conduct the *de novo* review and issue a decision. 42 C.F.R. § 405.1000(d).

Hearing on this matter was held on November 19, 2018, at which Debra Parrish, Esq., appeared on behalf of Mr. [REDACTED]. Julie Miles and Tim Parks, both RNs and Clinical Appeals Specialists with Novocure, also appeared. Exhibits 1-3 were admitted into the record without objection. Following presentation of the case, the record was closed and the hearing concluded.

² The record does not include the new patient order form for Optune. (See Exh. 2).

³ http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100034a.pdf.

⁴ http://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034S013a.pdf.

⁵ Stupp, Roger, M.D. et al., *Maintenance Therapy With Tumor-Treating Field Plus Temozolomide vs Temozolomide Alone for Glioblastoma A Randomized Clinical Trial*, 314 JAMA 2535 (2015).

The issues before the ALJ include all the issues brought out in the initial determination, coverage determination, or organization determination; redetermination; or reconsideration that were not decided entirely in the Appellant's favor, for the claims or other appealed matters specified in the request for hearing. The issue was whether all Medicare coverage requirements have been met warranting payment for the Tumor Treatment Field Therapy.

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with the decisions of the Medicare contractor and the Qualified Independent Contractor is entitled to a hearing before the Secretary of the Department of Health and Human Services, Social Security Act § 1869(b)(1)(A), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner, 42 C.F.R. § 405.1002. The request for hearing is timely if filed within sixty days after receipt of a Qualified Independent Contractor decision. 42 C.F.R. § 405.1014(c). The minimum amount in controversy required for hearing before an Administrative Law Judge are published in the Federal Register.

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the Appellant's favor. 42 C.F.R. § 405.1032(a).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue and makes a decision based on the hearing record. 42 C.F.R. § 405.1000(d).

II. Principles of Law

A. Statutes and Regulations

Medicare Part B provides coverage to eligible beneficiaries for all or part of the cost of "medical and other health services," a term that is defined by the Social Security Act as including, among many other things, durable medical equipment. *See* Social Security Act § 1832(a)(1)(B); 42 C.F.R. § 410.10(h). Notwithstanding any other provision of Title XVIII of the Social Security Act, no payment may be made under parts A or B for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Social Security Act § 1862(a)(1)(A). Similarly, Medicare precludes payment to any claimant unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." Social Security Act § 1833(e).

B. Policy and Guidance

The Social Security Act vests in the Secretary the authority to make coverage decisions. Under that authority, CMS issues National Coverage Determinations (NCDs) that state whether specific medical items, services, treatment procedures, or technologies may be paid for by Medicare. In the absence of a specific NCD, the Medicare contractor is responsible for determining whether an item or service is reasonable and necessary. (See preface to Coverage Issues Manual (reprinted at 54 Fed. Reg. 34555 (Aug. 21, 1989)). Accordingly, in addition to looking to the binding statutory and regulatory authority, this ALJ must accord substantial deference to manuals, program memoranda and other issuances issued by the Center for Medicare and Medicaid Services (CMS) and its carriers and intermediaries. 42 C.F.R. § 405.1062. Thus, the ALJ looks to the Local Coverage Determinations (LCD), if any, and the Medicare Benefit Policy Manual.

Historically, in making coverage determinations, CMS has interpreted the terms "reasonable and necessary" to mean that the item or service in question is safe and effective and not experimental. CMS has further determined that the relevant tests for applying these terms are whether the item or service has been proven safe and effective based on authoritative evidence, or alternatively, whether the item or service is generally accepted in the medical community as safe and effective for the condition for which it is used. 54 Fed. Reg. 4304 (Jan. 30, 1989); 60 Fed. Reg. 48417 (Sept. 19, 1995); see also 52 Fed. Reg. 15,560 (Apr. 29, 1987). Indeed, CMS has provided guidance in the *Medicare Program Integrity Manual* (CMS Pub. 100-08) (*MPIM*) to assist contractors in developing LCDs to aid in creating relevant tests and guidance. The *MPIM* contemplates that, in making a determination as to whether an item or service is reasonable and necessary, contractors will analyze whether the item or service is safe and effective, and not experimental or investigational. *MPIM*, Ch. 13 at § 13.5.1. Contractors shall consider a service reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational; and
- Appropriate, including the duration and frequency that is considered appropriate for the service.

The *MPIM* further instructs contractors to base LCDs on the strongest evidence available at the time the determination is issued. In order of preference, this includes:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and ALJs and the Medicare Appeals Council are not bound by CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. 42 C.F.R. § 405.1062(a).

- General acceptance by the medical community (standards of practice), supported by sound medical evidence based on:

- o Scientific data or research studies published in peer-reviewed medical journals;

- o Consensus of expert medical opinion (i.e., recognized authorities in the field);
- or
- o Medical opinion derived from consultations with medical associations or other health care experts.

Id. at § 13.7.1. The Manual further explains:

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

Id.

There is a Local Coverage Determination stating CMS' guidance for Tumor Treatment Field Therapy: CGS Administrators, LLC, Local Coverage Determination, LCD L34823, Tumor Treatment Field Therapy (TTFT) (January 2017). This LCD provides, without elucidation, that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.⁶ The related Policy Article states that tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit and must meet the reasonable and necessary requirements set out in the related LCD to be eligible for reimbursement. CGS Administrators, LLC, Local Coverage Article for Tumor Treatment Field Therapy Article A52711 (Article A52711) (January 2017).

Analysis

The issue is whether the Appellant's services are entitled to coverage. Pursuant to section 405.1032(a) of the regulations (42 C.F.R.), the unfavorable findings of the contractors are the issues before this ALJ. The QIC found that based on the available documentation, Medicare requirements outlined in the LCD, NCD, and Medicare manuals were not met.

There is no NCD specific to tumor treatment field therapy. This ALJ, therefore, looks to the relevant LCD for guidance. ALJs are not bound by LCDs and will give substantial deference to the policies if they are applicable to a particular case. 42 C.F.R. § 405.1062. If an ALJ declines to follow an LCD in a particular case, the ALJ must explain the reasons why the policy was not followed. *Id.*

⁶ This latest version of the LCD, omits entirely the literature previously shown in the 2016 LCD (an update from the 2015 version, which is not markedly distinguishable).

In this case, this ALJ declines to follow LCD L34823 for multiple reasons. The therapy has been shown to be safe and effective for use in patients with recurrent glioblastoma (after chemotherapy, radiation and/or surgery has been tried without sufficient success)⁷, and it is medically reasonable and necessary to treat Mr. condition. Indeed, a review of the literature, and even news articles, indicate this is the standard of care to be applied to individuals.

The relevant LCD states that tumor treatment field therapy will be denied as not reasonable and necessary. This version of the LCD omits entirely the literature previously shown in the prior LCDs. In any event, the advancement of medicine and science can sometimes outpace the current or relevant version of an LCD. Subsequently reported data from the FDA, phase III clinical trials, and NCCN guidelines is available to this ALJ for review and analysis, and shows the LCD, at best, is behind the medical literature curve – at least as applied to this patient, Mr. . The more helpful and relevant Medicare guidance in this instance is the *Medicare Program Integrity Manual* (CMS Pub. 100-08) (*MPIM*), which provides the more appropriate and helpful guidance for making a determination as to whether an item or service is reasonable and necessary, and not experimental or investigational. *MPIM*, Ch. 13 at § 13.5.1.

Applying that guidance, this ALJ first finds that the Optune device received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011. On October 5, 2015, the FDA gave premarket approval for use of Optune in patients with newly diagnosed glioblastoma. The FDA website explains that premarket approval (PMA) entails the following:

PMA is the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).⁸

While FDA premarket approval does not establish that the device is medically reasonable and necessary pursuant to Medicare requirements, it does ensure that the FDA has closely examined the device and its application. In this case, the FDA determined that sufficient scientific evidence existed to provide the FDA with assurance that the device was safe and effective for its intended use both in patients with recurrent and newly diagnosed glioblastoma. From this perspective, the use of the device meets Medicare guidance requiring that a device be proven safe and effective based on authoritative evidence.

The FDA approval, along with the other evidence below, also helps shows that the device is safe, and not experimental or investigational. Medicare does not pay for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to

⁷ No medical documentation was submitted that showed Mr. response to standard care chemo-radiation therapy and temozolomide. However, since he continued on with TTF therapy after three months of standard care chemo-radiation and temozolomide treatment, it is reasonable to assume that the conventional treatment was not sufficiently successful.

⁸<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm>

improve the functioning of a malformed body member. Social Security Act § 1862(a)(1). To be reasonable and necessary, the procedure must be safe and effective and not experimental.

Second, this ALJ has reviewed clinical studies in the record related to the use of the Optune device. Results from a phase III clinical trial utilizing TTFT in patients with recurrent glioblastoma was shown to have equivalent efficacy when compared to the best physician's choice for chemotherapy. With respect to patients newly diagnosed with glioblastoma, results of a phase III study released in a December 15, 2015, JAMA article showed that adding TTFT to maintenance temozolomide significantly prolonged progression-free and overall survival. Significantly, patients in the control group in the JAMA-reported study crossed over to the combined therapy group for TTFT treatment due to the improvement in outcomes seen. The results from these phase III trials also led to FDA approval for the Optune device. Again, these trials showed that the Optune device was safe, non-investigational and effective. It is noteworthy that the 2015 study contains proof of efficacy. In contrast, the LCD lacks any substantive guidance, analysis, or even recent citation to medical authority. In addition, these trials showed that the Optune device was appropriate for Mr. [redacted] needs, specifically the treatment of recurrent glioblastoma.

Third, the use of TTFT is generally accepted by the medical community. In the 2015 version of the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology Central Nervous System Cancers guidelines, alternating electric field therapy is a treatment option suggested for glioblastoma. This suggestion was found in a treatment guideline from a national cancer organization, not evidence based on an individual physician treating a single patient in a clinical setting. As such, TTFT treatment is generally accepted in the medical community as safe and effective for the treatment of recurrent glioblastoma.

Overall, a review of the literature available showed that the Optune device received FDA premarket approval, showing that it was safe and effective and not investigational/experimental. The use of the Optune device in a population with recurrent glioblastoma was proven effective and appropriate through a phase III clinical trial; and the use of the Optune device appears in national cancer treatment guidelines for treatment of glioblastoma, showing general acceptance by the medical community. A number of commercial health plans also now cover TTFT.

For the reasons stated above, this ALJ finds that Optune (TTFT) has been shown to be safe and effective, and is not experimental. Medicare coverage is thus available for tumor treatment field therapy.

Conclusions of Law

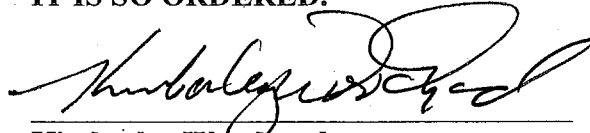
Medicare coverage exists for the Optune Tumor Treatment Field Therapy services (E0766) provided to the Beneficiary for dates of service September 15, 2017, October 15, 2017, and November 15, 2017.

Order

The Medicare Contractor shall process the claim in accord with this decision.

IT IS SO ORDERED.

Dated: NOV 20 2018


Kimberley Woodyard
U.S. Administrative Law Judge



Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

Kansas City Field Office
601 East 12th Street, Suite 221
Kansas City, MO 64106
816-599-3300 (Main)
816-599-3290 (ALJ Woodyard Team)
816-527-0115 (FAX)
844-566-6258 (Toll Free)

Date: January 9, 2017

ALJ Appeal Number: 1-5309926775

Appellant:

ATTN: JORGE MORALES
195 Commerce Way
Portsmouth, NH 03801

NOTICE OF DECISION

Enclosed is the Administrative Law Judge's decision for the above case. As explained below, the decision is binding unless it is appealed to the Medicare Appeals Council, or the Medicare Appeals Council reviews the case on its own motion.

This decision is based on the administrative record and any testimony presented to the Administrative Law Judge for the matter at issue. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. In addition, you may file either an oral or written Request for an Expedited Review with the Medicare Appeals Council if your appeal involves a coverage determination, is not solely a request for payment of a Part D drug already furnished, and your prescribing physician or other prescriber indicates, or the Medicare Appeals Council determines, that the standard time frame for rendering a decision may seriously jeopardize your life, health or ability to regain maximum function.

The Medicare Appeals Council may also decide to review the decision on its own motion. If you do not appeal the decision and the Medicare Appeals Council does not review the decision, the decision is binding and you will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.

How do I file an appeal if I want an expedited review?

You may request that your claim be expedited by calling the Medicare Appeals Council at (202) 565-0100 or 1-866-365-8204 (toll-free). An expedited review will be granted only if your appeal involves a coverage determination, is not solely a request for payment of a Part D drug already furnished, and your prescribing physician or other prescriber indicates, or the Medicare Appeals Council determines, that the standard time frame for rendering a decision may seriously jeopardize your life, health or ability to regain maximum function.

How much time do I have to file an appeal?

The Medicare Appeals Council must receive your appeal **within 60 days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

Additional information about filing an appeal with the Medicare Appeals Council is available at <http://www.hhs.gov/dab/>. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or 1-866-365-8204 (toll-free), if you have questions about filing an appeal.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing, unless it is an oral Request for an Expedited Review. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree.

You may submit your request for review using one of three available methods: mail, fax, or electronic file (E-File). **Please do not submit your request for review using more than one method.** Regardless of how you file your appeal, **you must always send a copy of your request for review to the other parties who received a copy of this decision.**

By mail:

You can do this by completing the enclosed *Request for Review* (Form DAB-101), or by writing a letter containing the following:

- The enrollee's name and telephone number;
- The enrollee's health insurance claim number (HICN);
- The plan name;
- The ALJ appeal number;
- The specific Part D drug(s) for which the review is requested;
- A statement that the enrollee is requesting an expedited review, if applicable; and
- The enrollee's name and signature, or, if applicable, the name and signature of your representative.

Mail your appeal and a copy of the decision to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

By fax to (202) 565-0227.

By E-File on the Medicare Operations Division Electronic Filing System (MOD E-File), available at <https://dab.efile.hhs.gov/mod>. To file a new appeal using MOD E-File, you will need to register by:

- (1) Clicking **Register** on the MOD E-File home page;
- (2) Entering the information requested on the "Register New Account" form; and
- (3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at <https://dab.efile.hhs.gov/mod/users/new>. You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party's representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

- (1) Logging into MOD E-File;
- (2) Clicking the **File New Appeal** menu button on the top right of the screen;
- (3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
- (4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the "File New Appeal – Medicare Operations Division" form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed decision. All documents should be submitted in Portable Document Format (PDF) whenever possible. Any document, including a Request for Review, will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.

Currently, the documents that may be filed electronically are the:

- (1) Request for Review;
- (2) Appointment of Representative form (OMB Form 0938-0950);
- (3) Copy of ALJ decision/dismissal order;
- (4) Memorandum or brief or other written statement in support of your appeal; and
- (5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to the Administrative Law Judge for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll free phone number and mailing address are at the top of this notice.

Copies were sent to the following:

ATTN: JORGE MORALES
195 Commerce Way
Portsmouth, NH 03801

Humana Insurance Company
Humana Medical Plan, Inc.
PO Box 14165
Lexington, KY 49512-4165

Appeals Work Station
Maximus Federal Services
Medicare Part C QIC
3750 Monroe Ave., Suite 702
Pittsford, NY 14534-1302

Enclosures:

Form DAB-101, Request for Review



**Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, MO**

Appeal of:	ALJ Appeal No.: 1-5309926775
Beneficiary:	Medicare: Part C
HICN:	Before: Kimberley Woodyard Administrative Law Judge

DECISION

Upon a *de novo* review of the record in this case, and following hearing, this Administrative Law Judge enters a **FAVORABLE** decision for . Humana Insurance Company shall pre-approve tumor treatment field therapy for

Procedural History

This appeal is before this Administrative Law Judge following prior adverse decisions of the Plan and Quality Improvement Organization, both of which denied approval of the proposed treatment. The reconsideration decision was issued on October 28, 2016, after which the Appellant filed a request for hearing before an Administrative Law Judge, on November 2, 2016.

Inasmuch as the request was timely and the amount in controversy meets the jurisdictional requirements for an ALJ hearing, 42 C.F.R. §§ 422.600, 422.602, this ALJ has jurisdiction to conduct the *de novo* review, 42 C.F.R. § 405.1000(d), and issue a decision.

Hearing on this matter was held on December 29, 2016, at which Jorge Morales, the Beneficiary's representative appeared. Humana appeared by Dr. Bruce Neibylski. Exhibits 1-4 were admitted into evidence without objection. Upon conclusion of argument and testimony, the record was closed and the hearing was concluded.

Issue

This issue is whether all plan contract coverage requirements have been met warranting payment under Title XVIII of the Social Security Act.

Findings of Fact

This Judge finds the following facts to be established by the evidence in the record:

1. [redacted] is a sixty-eight year-old man suffering from glioblastoma of the right temporal lobe. (Exh. 3, p. 3). This is a particularly aggressive malignant primary brain tumor, (Exh. 3, p. 21), with which he was diagnosed on April 8, 2015, (Exh. 3, p. 3).
2. On August 31, 2016, Dr. Dina Randazzo signed a prescription for [redacted] to receive six months of Optune -- treatment to start ASAP. (Exh. 3, p. 1).
3. [redacted] had already undergone, among other treatments, six months of radiation with concurrent temozolomide. (Exh. 3, p. 3). He continued, however, to have seizures and staring spells. (Exh. 3, p. 4). His symptoms had gotten worse since his last appointment, but were still better than several months prior, following the radiation. *Id.* [redacted] is also inflicted with diabetes and hypertension. *Id.* At his doctor visit of August 31, 2016, the heterogeneous mass in his right anterior temporal lobe that had minimally increased. *Id.* at 8. The tumor was progressive. *Id.* In light of the clinical and radiographic continued progression of the disease, Dr. Randazzo recommended that [redacted] initiate the use of Optune, and she began the paperwork for him. *Id.* The documentation of the continued progression is also supported by the physician notes of the prior encounter of August 3, 2016. (Exh. 3, pp. 11-16).
4. Optune uses low-intensity electric fields to help slow or stop glioblastoma cancer cells from dividing. See <https://www.optune.com/therapy/how-therapy-works>. Four adhesive patches, or transducer arrays, are applied to the scalp and connected to the device and a battery to deliver the therapy. *Id.*
5. Optune, previously called NovoTTF-100A System, received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011.¹
6. On October 5, 2015, the Provider received premarket approval from the FDA for use of Optune in patients newly diagnosed with glioblastoma.² The FDA approval was based upon the premarket approval process, not the abbreviated 510(k) clearance process.
7. On December 15, 2015, the Journal of the American Medical Association ("JAMA") published an article analyzing the results of a phase III clinical trial related to TTFT. Stupp, Roger, M.D. et al., *Maintenance Therapy With Tumor-Treating Field Plus Temozolomide vs Temozolomide Alone for Glioblastoma A Randomized Clinical Trial*, 314 JAMA 2535 (2015); (Exh. 3, pp. 22, et seq.). The analysis of the clinical trial showed that adding TTFT to maintenance temozolomide in a population with new onset glioblastoma "significantly prolonged progression-free and overall survival."
8. In an article published in July 2015 in Current Treatment Options in Oncology, results of a phase III clinical trial for recurrent glioblastoma were discussed, as well as interim

¹ http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100034a.pdf.

² http://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034S013a.pdf.

results in a study involving patients newly diagnosed with glioblastoma. *See* 16 Curr. Treat. Options in Oncol. 40 (2015); (Exh. 3, pp. 57 *et seq.*). This article reported that TTFT was “shown to have equivalent efficacy when compared to the best physician’s choice chemotherapy in a registration phase III clinical trial for recurrent glioblastoma.” *Id.* The results of this clinical trial then led to FDA approval for the device. *Id.* Interim results of a later clinical trial for newly diagnosed patients showed significant improvement in outcomes of the patients, leading to crossover of trial subjects from the control group to the experimental group. *Id.*

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with the decisions of the Medicare contractor and the Qualified Independent Contractor is entitled to a hearing before the Secretary of the Department of Health and Human Services, Social Security Act § 1869(b)(1)(A), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner, 42 C.F.R. § 422.602. The request for hearing is timely if filed within sixty days of the reconsideration determination. *Id.* The minimum amount in controversy required for hearing before an Administrative Law Judge are published in the Federal Register. In this instance, this ALJ uses the projected value of the services to compute the amount in controversy. 42 C.F.R. § 422.600(c).

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the Appellant’s favor. 42 C.F.R. § 405.1032(a).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue and makes a decision based on the hearing record. 42 C.F.R. § 405.1000(d).

II. Principles of Law

A. The Statutes and Regulations

Sections 1812 and 1813 of the Act establish the scope of benefits of the hospital insurance program under Medicare Part A. Section 1814 establishes conditions for, and limitations on, payment for services furnished by providers. Medicare coverage for hospitalization includes payment for the services generally available in a hospital: bed and board, nursing services and other related services, use of hospital facilities, medical social services, drugs, supplies and equipment, diagnostic or therapeutic items or services, and medical or surgical services provided by certain interns and residents pursuant to section 1861(b) of the Act. In addition, section 1861 defines hospitals to include institutions which provide “therapeutic services for medical diagnosis, treatment and care of injured, disabled, or sick persons, or rehabilitation or injured, disabled or sick persons.” Section 1862(a)(1)(A), prohibits Medicare

payments for anything which is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

In the event the services are found to be “not medically reasonable and necessary” or “custodial in nature” under section 1862(a)(1) or (a)(9) of the Act, section 1879 provides for limitation on liability for Medicare payments. If the beneficiary had no knowledge that the services would not be covered, but the provider of the services did, then the provider is liable and cannot seek or retain payment by the beneficiary. The regulations at 42 C.F.R. § 411.400 *et seq.* and HCFA Ruling 95-1 address how to determine if the beneficiary or provider/supplier had the requisite degree of knowledge to make them liable under section 1879. *See also* CMS, Medicare Claims Processing Manual (MCPM), Internet-Only Manual Pub. 100-4, Ch. 30, § 20. In general, the existence of a notice, manual, or community medical standard is sufficient to constitute notice as applicable to the provider. 42 C.F.R. § 411.406.

An MA plan must provide an enrollee with coverage for all items and services covered by Medicare Part A (except hospice services) and Part B that are available to beneficiaries in the plan's service area. *See* Section 1852 (a) (1) of the Social Security Act (Act); 42 C. F. R. §§ 422.100 (c) (1); 422.101 (a). An MA plan must comply with National Coverage Determinations (NCDs), general coverage guidelines included in original Medicare manuals and instructions, and written coverage decisions of local Medicare contractors with jurisdiction over claims in the geographic area in which services are covered under the MA plan. 42 C.F.R. § 422.101(b). Therefore, if Medicare does not cover an item or service, unless the plan covers the item or service through supplemental benefits, the Plan is not required cover the item or service at issue. *See* 42 C.F.R. § 422.102.

B. Policy and Guidance

The Social Security Act vests in the Secretary the authority to make coverage decisions. Under that authority, CMS issues National Coverage Determinations (NCDs) that state whether specific medical items, services, treatment procedures, or technologies may be paid for by Medicare. In the absence of a specific NCD, the Medicare contractor is responsible for determining whether an item or service is reasonable and necessary. (See preface to Coverage Issues Manual (reprinted at 54 Fed. Reg. 34555 (Aug. 21, 1989)). Accordingly, in addition to looking to the binding statutory and regulatory authority, this ALJ must accord substantial deference to manuals, program memoranda and other issuances issued by the Center for Medicare and Medicaid Services (CMS) and its carriers and intermediaries. 42 C.F.R. § 405.1062. Moreover, an ALJ may not set aside or review the validity of a local coverage policy in the context of a claim appeal. 42 C.F.R. § 405.1062(c). Thus, the ALJ looks to the Local Coverage Determinations (LCD), if any, and the Medicare Benefit Policy Manual.

In this instance, there is an LCD, to wit Tumor Treatment Field Therapy (TTFT)(L34823). With regard to medical necessity, it provides in full:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this local coverage determination, the criteria for “reasonable and necessary,” based

on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

For an item to be covered by Medicare, a detailed written order (DWO) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed DWO, the item will be denied as not reasonable and necessary.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

LCD 34823 (Effective July 1, 2016).³ The language in the LCD prior to this effective date is identical. LCD 34823 (effective 10/01/2015 – 7/01/2016).

Historically, in making coverage determinations, CMS has interpreted the terms "reasonable and necessary" to mean that the item or service in question is safe and effective and not experimental. CMS has further determined that the relevant tests for applying these terms are whether the item or service has been proven safe and effective based on authoritative evidence, or alternatively, whether the item or service is generally accepted in the medical community as safe and effective for the condition for which it is used. 54 Fed. Reg. 4304 (Jan. 30, 1989); 60 Fed. Reg. 48417 (Sept. 19, 1995); see also 52 Fed. Reg. 15,560 (Apr. 29, 1987). Indeed, CMS has provided guidance in the *Medicare Program Integrity Manual* (CMS Pub. 100-08) (*MPIM*) to assist contractors in developing LCDs to aid in creating relevant tests and guidance. The *MPIM* contemplates that, in making a determination as to whether an item or service is reasonable and necessary, contractors will analyze whether the item or service is safe and effective, and not experimental or investigational. *MPIM*, Ch. 13 at § 13.5.1. Contractors shall consider a service reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational; and
- Appropriate, including the duration and frequency that is considered appropriate for the service.

The *MPIM* further instructs contractors to base LCDs on the strongest evidence available at the time the determination is issued. In order of preference, this includes:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and ALJs and the Medicare Appeals Council are not bound by CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. 42 C.F.R. § 405.1062(a).

- General acceptance by the medical community (standards of practice), supported by sound medical evidence based on:

- o Scientific data or research studies published in peer-reviewed medical journals;
- o Consensus of expert medical opinion (i.e., recognized authorities in the field);

or

³ Mr. Chason made his authorization request on September 6, 2016. (Exh. 2, p. 23).

o Medical opinion derived from consultations with medical associations or other health care experts.

Id. at § 13.7.1. The Manual further explains:

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

Id.

C. The Terms of the Plan (Evidence of Coverage)

The insurance plan that governs this proceeding is located in Exhibit 1 and provides that it covers services in accord with Medicare rules. (Exh. 1, p. 53). The services “*must* be medically necessary,” which means that the services are “needed for the prevention, diagnosis, or treatment of your medical condition and meet accepted standards of medical practice.” (Exh. 1, p. 35)(emphasis in original). The plan charts what services are not covered, including, “Services considered not reasonable and necessary, according to the standards of Original Medicare.” (Exh. 1, p. 87). Another exclusion is: “Experimental medical and surgical procedures, equipment and medications. Experimental procedures and items are those items and procedures determined by our plan and Original Medicare to not be generally accepted by the medical community.” *Id.*

Analysis

seeks a decision requiring Humana Insurance Company) to pre-approve tumor treatment field therapy, asserting that the services are not experimental for his diagnosis. The Plan argued that the relevant Local Coverage Determination stated that Tumor Treatment Field Therapy was not covered by Medicare as not medically reasonable and necessary treatment. The MA Plan is bound to follow Local Coverage Determinations.

has a brain tumor that has failed other treatment and, accordingly, seeks treatment – Tumor Treatment Field Therapy. He has been through radiation and other treatment and yet his disease is progressing. Medicare, through its contractor, has issued a policy statement to which this ALJ, in the first instance, is required to accord “substantial deference.” In order to deviate from that guidance, the specific LCD applicable to this case, I must have a cogent explanation for disregarding that guidance. *See* 42 C.F.R. § 405.1062. In this instance, the grounds for disregarding the LCD are copious and warranted. The therapy has been shown to be safe and effective for use in patients with recurrent glioblastoma (after other treatments have been tried without sufficient success, all as here) and it is medically reasonable and necessary to treat Mr. Chason’s brain condition.

The relevant LCD states that tumor treatment field therapy will be denied as not reasonable and necessary. However, the Information and Basis of Decision section of the applicable version LCD showed that the most recent literature reviewed for purposes of the LCD’s formation was published in 2013. If additional or more recent literature was reviewed, it is not listed in the LCD. LCD L34823. In any event, the advancement of medicine and science

can sometimes outpace the current or relevant version of an LCD. In this case, the advancement is obvious. Indeed, subsequently reported data from the FDA, phase III clinical trials, and NCCN guidelines is available to this ALJ for review and analysis, and shows the LCD may be behind the medical literature curve as applied to this patient.

The Optune device received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011. On October 5, 2015, the FDA gave premarket approval for use of Optune in patients with newly diagnosed glioblastoma. The FDA website explains that premarket approval (“PMA”) entails the following:

PMA is the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).⁴

While FDA premarket approval does not establish that the device is medically reasonable and necessary pursuant to Medicare requirements, it does ensure that the FDA has closely examined the device and its application. In this case, the FDA determined that sufficient scientific evidence existed to provide the FDA with assurance that the device was safe and effective for its intended use both in patients with recurrent and newly diagnosed glioblastoma. From this perspective, the use of the device meets Medicare guidance requiring that a device be proven safe and effective based on authoritative evidence.

The FDA approval also helps shows that the device is safe, and not experimental or investigational Medicare does not pay for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. Social Security Act § 1862(a)(1). To be reasonable and necessary, the procedure must be safe and effective and not experimental.⁵

Second, this ALJ has reviewed clinical studies in the record related to the use of the Optune device. Results from a phase III clinical trial utilizing TTFT in patients with recurrent glioblastoma was shown to have equivalent efficacy when compared to the best physician’s choice for chemotherapy. With respect to patients newly diagnosed with glioblastoma, results of a phase III study released in a December 15, 2015, JAMA article showed that adding TTFT to maintenance temozolomide significantly prolonged progression-free and overall survival. *Id.* Significantly, patients in the control group in the JAMA-reported study crossed over to the combined therapy group for TTFT treatment due to the improvement in outcomes seen. *Id.* The results from these phase III trials also led to FDA approval for the Optune device. *Id.* Again, these trials showed that the Optune device was safe, non-investigational and effective. In

⁴<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm>.

⁵ This ALJ is mindful of the distinction between FDA approval and Medicare’s “reasonable and necessary” criteria. The FDA concentrates on the safety of a device or procedure, whereas Medicare reviews whether the procedure meets the broader requirement, “reasonable and necessary.” These entities make determinations under different statutory standards as well as different delegated authority. *See generally* 68 Fed. Reg. 55,636, 54 Fed. Reg. 4307. FDA approval does not generally entitle a procedure to coverage. 68 Fed. Reg. 55,636.

addition, these trials showed that the Optune device was appropriate for [REDACTED]; individual needs, specifically the treatment of recurrent glioblastoma.

Third, the use of TTFT is generally accepted by the medical community. In the 2015 version of the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology Central Nervous System Cancers guidelines, alternating electric field therapy is a treatment option suggested for glioblastoma. This suggestion was found in a treatment guideline from a national cancer organization, not evidence based on an individual physician treating a single patient in a clinical setting. As such, this ALJ finds that TTFT treatment is generally accepted in the medical community as safe and effective for the treatment of recurrent glioblastoma.

Overall, a review of the literature available demonstrates that the Optune device received FDA premarket approval, and that it is safe and effective and not investigational/experimental. The use of the Optune device in a population with recurrent glioblastoma was proven effective and appropriate through a phase III clinical trial; and the use of the Optune device appears in national cancer treatment guidelines for treatment of glioblastoma, showing general acceptance by the medical community. A number of commercial health plans also now cover TTFT.

The final aspect is the medical record of [REDACTED], whose disease, without this treatment, will likely progress to cause an earlier death than need be the case. A review of the medical records and hearing demonstrated that [REDACTED] has already undergone extensive treatment for the cancer and there appear to be no further options; the disease is progressing despite the treatments. [REDACTED] has no alternative care available to halt the progression of the disease. The preponderance of the evidence is that TTFT therapy is warranted to battle the progression of disease and prolong his life.

Conclusions of Law

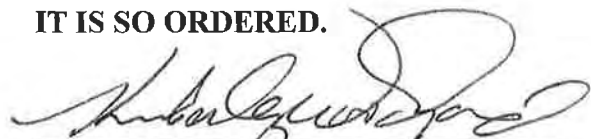
[REDACTED] insurance benefits are determined by the terms of his Medicare Advantage PPO plan with a Medicare contract. Under the terms of the plan, Medicare rules and coverage determinations guide whether an item or device will be covered. In order for coverage to exist, a procedure must be medically reasonable and necessary. Optune (TTFT) has been shown to be safe and effective and is medically reasonable and necessary for the treatment of Mr. [REDACTED] condition. Plan coverage is warranted.

Order

The Medicare Contractor is DIRECTED to process the request for pre-approval of the treatment in accord with this decision.

IT IS SO ORDERED.

Dated: JAN 9 2016



Kimberley Woodyard
U.S. Administrative Law Judge

REQUEST FOR REVIEW OF ADMINISTRATIVE LAW JUDGE (ALJ) MEDICARE DECISION / DISMISSAL

1. APPELLANT (the party requesting review)

2. ALJ APPEAL NUMBER (on the decision or dismissal)

3. BENEFICIARY*

4. HEALTH INSURANCE CLAIM NUMBER (HICN)*

*If the request involves multiple claims or multiple beneficiaries, attach a list of beneficiaries, HICNs, or other information to identify all claims being appealed.

5. PROVIDER, PRACTITIONER, OR SUPPLIER

6. SPECIFIC ITEM(S) OR SERVICE(S)

7. Medicare claim type: ☐ Part A ☐ Part B ☐ Part C - Medicare Advantage
☐ Part D - Medicare Prescription Drug Plan ☐ Entitlement/enrollment for Part A or Part B

8. Does this request involve authorization for an item or service that has not yet been furnished?

☐ Yes If Yes, skip to Block 8.
☐ No If No, Specific Dates of Service:

9. If the request involves authorization for a prescription drug under Medicare Part D, would application of the standard appellate timeframe seriously jeopardize the beneficiary's life, health, or ability to regain maximum function (as documented by a physician) such that expedited review is appropriate? ☐ Yes ☐ No

I request that the Medicare Appeals Council review the ALJ's ☐ decision or ☐ dismissal order [check one] dated _____. I disagree with the ALJ's action because (specify the parts of the ALJ's decision or dismissal you disagree with and why you think the ALJ was wrong):

(Attach additional sheets if you need more space)

PLEASE ATTACH A COPY OF THE ALJ DECISION OR DISMISSAL ORDER YOU ARE APPEALING.

DATE			DATE		
APPELLANT'S SIGNATURE (the party requesting review)			REPRESENTATIVE'S SIGNATURE (include signed appointment if not already submitted.)		
PRINT NAME			PRINT NAME		
ADDRESS			ADDRESS		
CITY, STATE, ZIP CODE			CITY, STATE, ZIP CODE		
TELEPHONE NUMBER	FAX NUMBER	E-MAIL	TELEPHONE NUMBER	FAX NUMBER	E-MAIL

(SEE FURTHER INSTRUCTIONS ON PAGE 2)

If you have additional evidence, submit it with this request for review. If you need more time, you must request an extension of time in writing now, explaining why you are unable to submit the evidence or legal argument now.

If you are a provider, supplier, or a beneficiary represented by a provider or supplier, and your case was reconsidered by a Qualified Independent Contractor (QIC), the Medicare Appeals Council will not consider new evidence related to issues the QIC has already considered unless you show that you have a good reason for submitting it for the first time to the Medicare Appeals Council.

IMPORTANT: Include the HICN and ALJ Appeal Number on any letter or other material you submit.

This request must be received within 60 calendar days after you receive the ALJ's decision or dismissal, unless we extend the time limit for good cause. We assume you received the decision or dismissal 5 calendar days after it was issued, unless you show you received it later. If this request will not be received within 65 calendar days from the date on the decision or dismissal order, please explain why on a separate sheet.

You must file your request for review in writing with the Medicare Appeals Council at:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

You may send the request for review by U.S. Mail, a common carrier such as FedEx, or by fax to (202) 565-0227. If you send a fax, please do not also mail a copy. **You must send a copy of your appeal to the other parties and indicate that all parties, to include all beneficiaries, have been copied on the request for review. For claims involving multiple beneficiaries, you may submit a copy of the cover letters issued or a spreadsheet of the beneficiaries and addresses who received a copy of the request for review.**

If you have any questions about your request for review or wish to request expedited review of a claim involving authorization of your prescription drug under Medicare Part D, you may call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100. You may also visit our web site at www.hhs.gov/dab for additional information on how to file your request for review.

PRIVACY ACT STATEMENT

The collection of information on this form is authorized by the Social Security Act (section 205(a) of title II, section 702 of title VII, section 1155 of Title XI, and sections 1852(g)(5), 1869(b)(1), 1871, 1872, and 1876(c)(5)(B) of title XVIII, as appropriate). The information provided will be used to further document your claim. Information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your claim. Information you furnish on this form may be disclosed by the Department of Health and Human Services or the Social Security Administration to another person or governmental agency only with respect to programs under the Social Security Act and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services, the Social Security Administration, or other agencies.



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, MO

Appeal of:	ALJ Appeal No.: 1-5309926775
Beneficiary:	Medicare: Part C
HICN:	Before: Kimberley Woodyard Administrative Law Judge

EXHIBIT LIST

EXHIBIT NUMBER	DESCRIPTION	PAGE NUMBERS
1	Evidence of Coverage	1-223
2	Organization Determination, MAO Reconsideration and Part C QIC Reconsidered Decision Procedural Documents	1-53
3	Medical Records/Evidence received by MAO and CMS contractors	1-105
4	Request for ALJ Hearing	1-4
5	OMHA Proceedings	1-22
6	Post-Hearing submission – Legal materials (not evidence)	1-87

Dated: January 7, 2017



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, Missouri

Appeal of:	ALJ Appeal No.: 1-7806941537
Beneficiary:	Medicare Part: B
DOS: 7/14/2017 8/14/2017 9/14/2017	
HICN:	Before: Kimberley Woodyard U.S. Administrative Law Judge

DECISION

Upon a *de novo* review of the record, this Administrative Law Judge enters a **FULLY FAVORABLE** decision for the Appellant, is entitled to coverage for Tumor Treatment Field Therapy (E0766).

**FINDINGS OF FACT AND
HISTORY OF THE CASE**

Mr. [redacted] forty-six years old at the time of services at issue, had suffered from brain tumors since 1996. (Exh. 3, pp. 4, 9). [redacted] MD, referred to Mr. [redacted] diagnosis as "oligodendroglioma." (Exh. 3, p. 3). However, he also referred to Mr. [redacted] diagnosis as "glioblastoma multiforme" (GBM).¹ (Exh. 3, p. 4).

In 1996, Mr. [redacted] underwent a gross total resection of his right frontal grade two oligodendroglioma, and was disease-free until 2004 when tumor progression was noted in the corpus callosum. (Exh. 3, p. 54). He underwent external beam radiation treatment along with concurrent temozolomide. *Id.* After completion of the external beam radiation treatment, in November 2004, he received six cycles of adjuvant temozolomide which was completed in June

¹ Both oligodendroglioma and glioblastoma are under the umbrella term of "glioma" brain tumors. <https://www.mayfieldclinic.com/PE-Glioma.htm>

2005. *Id.* He was on active surveillance with brain MRI scans every six months. *Id.* In February 2013, a brain MRI showed changes of possible progression in the left frontal lobe. *Id.* Various treatments were prescribed, including the use of temodar. (Exh. 3, p. 55). He finished chemotherapy in 2014. (Exh. 2, p. 56). In September 2016, a brain MRI compared to one done in April 2015, revealed more signal abnormality consistent with tumor progression. *Id.* Chemotherapy was recommended using CCNU (lomustine). *Id.* On October 5, 2016, Dr. [redacted] explained to Mr. [redacted] the dose, schedule, indication, side effects, adverse effects, and expected outcome for lomustine usage. (Exh. 2, p. 57). Dr. [redacted] also obtained consent for the Optune device, and noted in the medical record:

Optune is a first in class electromagnetic therapy FDA approved for both the indications of newly diagnosed Glioblastoma for initiation in combination with temozolomide or prescribing physician's best medical biochemotherapy recommendation. In the 'up front' setting, Optune is initiated approximately one month after completion of chemoRT. The treatment is indicated for longitudinal use through at least two other failed treatment plans as may be the case. Compliance of 80% or greater is essential. The device is also approved as a single intervention for treatment of recurrent / progressive malignant glioma.

Id.

On November 28, 2016, Mr. [redacted] had a follow-up visit with Dr. [redacted] (Exh. 3, p. 57). He was stable after one cycle of CCNU and had been wearing the Optune device for the prior three weeks. *Id.* He was "very compliant" with the Optune device. *Id.*

On December 15, 2016, Dr. [redacted] noted in his Letter of Medical Necessity that Mr. [redacted] had failed systematic chemotherapy and all radiotherapy options approved for his clinical situation, and that Mr. [redacted] was not a surgical candidate. (Exh. 3, p. 5). Dr. [redacted] determined that Optune tumor treatment field therapy (TTFT) was the only viable treatment option available to Mr. [redacted] because "Mr. [redacted] has exhausted essentially all FDA-approved treatments that could benefit him in this current clinical scenario. It is my belief that Optune is the only promising treatment option at the present time." (Exh. 3, p. 6). Dr. [redacted] also noted:

We are seeking to initiate Optune at the UF Health Cancer Center of Orlando. Our center has played a leadership role in clinical trials for this device and was one of the first hospitals in the nation to obtain manufacturer certification to use the device commercially following the FDA approval. We have successfully used Optune in appropriately selected patients with recurrent glioblastoma multiforme and believe the current patient is a good candidate for treatment.

(Exh. 3, p. 4).

On February 2, 2017, Mr. [redacted] third cycle of CCNU was held due to low blood counts. (Exh. 3, p. 57). On March 29, 2017, Dr. [redacted] reviewed the MRI, and found that the disease was stable. *Id.* He recommended that Mr. [redacted] receive the scheduled fourth of six

CCNU cycles; however, it was withheld due to labs indicating thrombocytopenia. (Exh. 3, pp. 57-58). Continuation with the Optune device was also recommended. (Exh. 2, p. 57). On May 31, 2017, Dr. [redacted] reviewed the latest MRI, and found disease progression. (Exh. 3, p. 58). Mr. [redacted] platelets were still too low to administer CCNU. *Id.* Dr. [redacted] recommended oral etoposide chemotherapy for cycles of seven days on and seven days off, in lieu of using CCNU. *Id.* The use of Avastin in the future was discussed in the event of disease progression, or screening for clinical research studies. *Id.* On July 31, 2017, an MRI revealed some increase in signal abnormality. (Exh. 3, p. 37). The continuing use of Optune was recommended, as well as oral etoposide. *Id.*

On March 23, 2017, Mr. [redacted] physician signed an Optune Prescription Form prescribing Optune treatment for Mr. [redacted] to start the week of April 5, 2017, for six months. (Exh. 3, p. 2). The record includes invoices for Optune for July 14, 2017, August 14, 2017, and September 14, 2017. (Exh. 2, pp. 95-97).

Optune treats cancer by using TTFT to interfere with the division of malignant cells. It is locally or regionally delivered, using alternating electric fields to disrupt the rapid cell division exhibited by cancer cells. (Exh. 2, p. 18). Optune with temozalomid is indicated for the treatment of adult patients with *newly diagnosed*, supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy. *Id.* However, for treatment of patients who have *recurrent* GBM, like Mr. [redacted]

Optune is indicated following histologically-confirmed or radiologically-confirmed recurrence in the supra-tentorial region of the brain after receiving chemotherapy. *Id.* The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted. *Id.*

Optune received pre-market approval from the FDA for treatment of glioblastoma in April 2011,² based upon the result of a large randomized, controlled trial of patients with recurrent GBM. (Exh. 2, pp. 43-47). The overall survival and progression-free survival to chemotherapy with minimal toxicity and an improvement in patients' quality of life, is demonstrated, compared to that of chemotherapy. *Id.*

In September 2012, results from a study were published comparing NovoTTF-100A (Optune) treatment to a physician's choice of chemotherapy treatment in recurrent glioblastoma cases.³ (Exh. 3, pp. 98-108). The study conclusions were summarized as:

This is the first controlled trial evaluating an entirely novel cancer treatment modality delivering electric fields rather than chemotherapy. No improvement in overall survival was demonstrated, however efficacy and activity with this chemotherapy-free treatment device appears comparable to chemotherapy

² http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100034a.pdf.

³ Stupp, Roger, M.D. et al., *NovoTTF-100A Versus Physician's Choice Chemotherapy In Recurrent Glioblastoma: A Randomized Phase III Trial Of A Novel Treatment Modality*, European Journal of Cancer, Volume 48, Issue 14, pp. 2192-2201 (September 2012).

regimens that are commonly used for recurrent glioblastoma. Toxicity and quality of life clearly favoured TTF.

(Exh. 2, p. 99).

On December 15, 2015, the Journal of the American Medical Association (JAMA) published an article analyzing the results of a phase III clinical trial related to TTFT.⁴ (Exh. 2, pp. 5-15). The analysis of the clinical trial showed that adding TTFT to maintenance temozolomide in a population with new onset glioblastoma “significantly prolonged progression-free and overall survival.” (Exh. 3, p. 13). After conclusion of the study, patients in the control group with ongoing maintenance therapy were offered TTFT therapy. (Exh. 3, p. 9).

The record also includes a National Comprehensive Cancer Network publication that provides clinical practice oncology guidelines.⁵ (Exh. 2, pp. 1-4). Alternating electric field therapy was considered an effective treatment option for recurrent glioblastomas and oligodendrogliomas. (Exh. 2, p. 4). Along with (1) palliative support care, (2) systemic chemotherapy, and (3) surgery or reirradiation, alternating electric field therapy is considered a fourth modality of cancer treatment. *Id.*

The Medicare Administrative Contractor, initially and on redetermination, denied the claim for the services. The Qualified Independent Contractor (QIC) denied reconsideration of the claim on June 13, 2018. Both the Administrative Contractor and the QIC found that, based on the available documentation, Medicare requirements outlined in the LCD were not met. Mr. filed a request for hearing before an Administrative Law Judge (ALJ) on July 27, 2018.⁶ Since the request was timely and the amount in controversy met the jurisdictional requirements for an ALJ hearing, 42 C.F.R. §§ 405.1002(a)(1), 405.1006(b)(1), this ALJ has jurisdiction to conduct the *de novo* review and issue a decision. 42 C.F.R. § 405.1000(d).

An ALJ may decide a case on the record without hearing if an examination of the record supports a finding in favor of the Appellant on every issue. 42 C.F.R. § 405.1038(a). Inasmuch as this ALJ issues this decision as wholly favorable, no hearing will be held.

The issues before the ALJ include all the issues brought out in the initial determination, coverage determination, or organization determination; redetermination; or reconsideration that were not decided entirely in the Appellant’s favor, for the claims or other appealed matters specified in the request for hearing. The issue was whether all Medicare coverage requirements have been met warranting payment for the Tumor Treatment Field Therapy.

⁴ Stupp, Roger, M.D. et al., *Maintenance Therapy With Tumor-Treating Field Plus Temozolomide vs Temozolomide Alone for Glioblastoma A Randomized Clinical Trial*, 314 JAMA 2535 (2015).

⁵ National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology, *Central Nervous System Cancers*, version 1.2016.

⁶ Mr. Starke’s attorney, Debra Parrish, also requested that two other cases involving services for Mr. be combined with this case. (Exh. 4, p. 5). However, the assignment of cases by OMHA to this ALJ only included the case at issue here. Thus, no combining can be accommodated.

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with the decisions of the Medicare contractor and the Qualified Independent Contractor is entitled to a hearing before the Secretary of the Department of Health and Human Services, Social Security Act § 1869(b)(1)(A), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner, 42 C.F.R. § 405.1002. The request for hearing is timely if filed within sixty days after receipt of a Qualified Independent Contractor decision. 42 C.F.R. § 405.1014(c). The minimum amount in controversy required for hearing before an Administrative Law Judge are published in the Federal Register.

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the Appellant's favor. 42 C.F.R. § 405.1032(a).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue and makes a decision based on the hearing record. 42 C.F.R. § 405.1000(d).

II. Principles of Law

A. Statutes and Regulations

Medicare Part B provides coverage to eligible beneficiaries for all or part of the cost of "medical and other health services," a term that is defined by the Social Security Act as including, among many other things, durable medical equipment. *See* Social Security Act § 1832(a)(1)(B); 42 C.F.R. § 410.10(h). Notwithstanding any other provision of Title XVIII of the Social Security Act, no payment may be made under parts A or B for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Social Security Act § 1862(a)(1)(A). Similarly, Medicare precludes payment to any claimant unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." Social Security Act § 1833(e).

B. Policy and Guidance

The Social Security Act vests in the Secretary the authority to make coverage decisions. Under that authority, CMS issues National Coverage Determinations (NCDs) that state whether specific medical items, services, treatment procedures, or technologies may be paid for by

Medicare. In the absence of a specific NCD, the Medicare contractor is responsible for determining whether an item or service is reasonable and necessary. (See preface to Coverage Issues Manual (reprinted at 54 Fed. Reg. 34555 (Aug. 21, 1989))). Accordingly, in addition to looking to the binding statutory and regulatory authority, this ALJ must accord substantial deference to manuals, program memoranda and other issuances issued by the Center for Medicare and Medicaid Services (CMS) and its carriers and intermediaries. 42 C.F.R. § 405.1062. Thus, the ALJ looks to the Local Coverage Determinations (LCD), if any, and the Medicare Benefit Policy Manual.

Historically, in making coverage determinations, CMS has interpreted the terms "reasonable and necessary" to mean that the item or service in question is safe and effective and not experimental. CMS has further determined that the relevant tests for applying these terms are whether the item or service has been proven safe and effective based on authoritative evidence, or alternatively, whether the item or service is generally accepted in the medical community as safe and effective for the condition for which it is used. 54 Fed. Reg. 4304 (Jan. 30, 1989); 60 Fed. Reg. 48417 (Sept. 19, 1995); see also 52 Fed. Reg. 15,560 (Apr. 29, 1987). Indeed, CMS has provided guidance in the *Medicare Program Integrity Manual* (CMS Pub. 100-08) (*MPIM*) to assist contractors in developing LCDs to aid in creating relevant tests and guidance. The *MPIM* contemplates that, in making a determination as to whether an item or service is reasonable and necessary, contractors will analyze whether the item or service is safe and effective, and not experimental or investigational. *MPIM*, Ch. 13 at § 13.5.1. Contractors shall consider a service reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational; and
- Appropriate, including the duration and frequency that is considered appropriate for the service.

The *MPIM* further instructs contractors to base LCDs on the strongest evidence available at the time the determination is issued. In order of preference, this includes:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and ALJs and the Medicare Appeals Council are not bound by CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. 42 C.F.R. § 405.1062(a).

- General acceptance by the medical community (standards of practice), supported by sound medical evidence based on:

- o Scientific data or research studies published in peer-reviewed medical journals;
- o Consensus of expert medical opinion (i.e., recognized authorities in the field);
- or
- o Medical opinion derived from consultations with medical associations or other health care experts.

Id. at § 13.7.1. The Manual further explains:

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

Id.

There is a Local Coverage Determination stating CMS' guidance for Tumor Treatment Field Therapy: CGS Administrators, LLC, Local Coverage Determination, LCD L34823, Tumor Treatment Field Therapy (TTFT) (January 2017). This LCD provides, without elucidation, that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.⁷ The related Policy Article states that tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit and must meet the reasonable and necessary requirements set out in the related LCD to be eligible for reimbursement. CGS Administrators, LLC, Local Coverage Article for Tumor Treatment Field Therapy Article A52711 (Article A52711) (January 2017).

Analysis

The issue is whether the Appellant's services are entitled to coverage. Pursuant to section 405.1032(a) of the regulations (42 C.F.R.), the unfavorable findings of the contractors are the issues before this ALJ. Both the Medicare Contractor and the QIC found, that based on the available documentation, Medicare requirements outlined in the LCD were not met. (Exh. 1, pp. 4, 41).

There is no NCD specific to TTFT. This ALJ, therefore, looks to the relevant LCD for guidance. ALJs are not bound by LCDs and will give substantial deference to the policies if they are applicable to a particular case. 42 C.F.R. § 405.1062. If an ALJ declines to follow an LCD in a particular case, the ALJ must explain the reasons why the policy was not followed. *Id.*

In this case, this ALJ declines to follow LCD L34823 for multiple reasons. The therapy has been shown to be safe and effective for use in patients with recurrent glioblastoma (after chemotherapy, radiation and/or surgery has been tried without sufficient success), and it is medically reasonable and necessary to treat Mr. condition.

The relevant LCD states that tumor treatment field therapy will be denied as not reasonable and necessary. This version of the LCD omits entirely the literature previously shown in the prior LCDs. In any event, the advancement of medicine and science can sometimes

⁷ This latest version of the LCD, omits entirely the literature previously shown in the 2016 LCD (an update from the 2015 version, which is not markedly distinguishable).

outpace the current or relevant version of an LCD. Subsequently reported data from the FDA, phase III clinical trials, and NCCN guidelines is available to this ALJ for review and analysis, and shows the LCD, at best, is behind the medical literature curve – at least as applied to this patient, Mr. [redacted].

The more helpful and relevant Medicare guidance in this instance is the *Medicare Program Integrity Manual* (CMS Pub. 100-08) (*MPIM*), which provides the more appropriate and helpful guidance for making a determination as to whether an item or service is reasonable and necessary, and not experimental or investigational. *MPIM*, Ch. 13 at § 13.5.1.

Applying that guidance, this ALJ first finds that the Optune device received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011. Additionally, on October 5, 2015, the FDA gave premarket approval for use of Optune in patients with newly diagnosed glioblastoma. The FDA website explains that premarket approval (PMA) entails the following:

PMA is the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).⁸

While FDA premarket approval does not establish that the device is medically reasonable and necessary pursuant to Medicare requirements, it does ensure that the FDA has closely examined the device and its application. In this case, the FDA determined that sufficient scientific evidence existed to provide the FDA with assurance that the device was safe and effective for its intended use both in patients with recurrent and newly diagnosed glioblastoma. From this perspective, the use of the device meets Medicare guidance requiring that a device be proven safe and effective based on authoritative evidence.

The FDA approval, along with the other evidence below, also helps show that the device is safe, and not experimental or investigational. Medicare does not pay for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. Social Security Act § 1862(a)(1). To be reasonable and necessary, the procedure must be safe and effective and not experimental.

Second, this ALJ has reviewed clinical studies in the record related to the use of the Optune device. Results from a phase III clinical trial utilizing TTFT in patients with recurrent glioblastoma was shown to have equivalent efficacy when compared to the best physician's choice for chemotherapy. With respect to patients newly diagnosed with glioblastoma, results of a phase III study released in a December 15, 2015, JAMA article showed that adding TTFT to maintenance temozolomide significantly prolonged progression-free and overall survival. Significantly, patients in the control group in the JAMA-reported study crossed over to the combined therapy group for TTFT treatment due to the improvement in outcomes seen. The results from these phase III trials also led to FDA approval for the Optune device. Again, these trials showed that the Optune device was safe, non-investigational and effective. It is noteworthy

⁸<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm>

that the 2015 study contains proof of efficacy. In contrast, the LCD lacks any substantive guidance, analysis, or even recent citation to medical authority. In addition, these trials showed that the Optune device was appropriate for Mr. [redacted] needs, specifically the treatment of recurrent glioblastoma.

Third, the use of TTFT is generally accepted by the medical community. In the 2015 version of the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology Central Nervous System Cancers guidelines, alternating electric field therapy is a treatment option suggested for glioblastoma. This suggestion was found in a treatment guideline from a national cancer organization, not evidence based on an individual physician treating a single patient in a clinical setting. As such, TTFT treatment is generally accepted in the medical community as safe and effective for the treatment of recurrent glioblastoma.

Overall, a review of the literature available showed that the Optune device received FDA premarket approval, showing that it was safe and effective and not investigational/experimental. The use of the Optune device in a population with recurrent glioblastoma was proven effective and appropriate through a phase III clinical trial; and the use of the Optune device appears in national cancer treatment guidelines for treatment of glioblastoma, showing general acceptance by the medical community. A number of commercial health plans also now cover TTFT.

For the reasons stated above, this ALJ finds that Optune (TTFT) has been shown to be safe and effective, and is not experimental. Medicare coverage is thus available for tumor treatment field therapy.

Conclusions of Law

Medicare coverage exists for the Optune Tumor Treatment Field Therapy services (E0766) provided to the Beneficiary for dates of service July 14, 2017, August 14, 2017, and September 14, 2017.

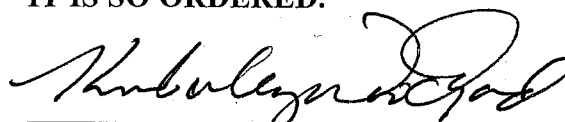
Order

The Medicare Contractor shall process the claim in accord with this decision.

IT IS SO ORDERED.

DEC 21 2018

Dated: _____



Kimberley Woodyard
U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Irvine Field Office
Irvine, CA

10/2/14

Appeal of: **Novocure**

ALJ Appeal No.: **1-6586389812**

Enrollee/Beneficiary

Medicare: **Part C**

HICN: **1619A**

Before: **Dean R. Yanohira**
U.S. Administrative Law Judge

DECISION

After careful consideration of the evidence and arguments presented, a **FULLY FAVORABLE** decision is entered for Novocure ("Appellant/Provider").

Procedural History

("Enrollee/Beneficiary") requested continued authorization from her health plan Priority Health ("Health Plan") for an electrical stimulation device used for cancer treatment (HCPCS E0766) provided by the Appellant/Provider beginning in May of 2017. On May 4, 2017, the Plan's Medical Doctor denied the request because the information submitted failed to meet medical necessity criteria of Local Coverage Determination (LCD) L34823 for Tumor Treatment Field Therapy ("TTFT"). (Exh. 1, pg. 25)

The Enrollee/Beneficiary requested reconsideration from Maximus Federal Services (MAXIMUS), a Medicare Qualified Contractor (the "QIC"). In an unfavorable decision dated June 12, 2017, the denial of coverage on the basis that the medical records did not meet the requirements of Local Coverage Determination (LCD) L34823. (Exh. 6).

The Appellant/Provider timely requested a hearing before an Administrative Law Judge to review MAXIMUS' denial of Medicare Part C benefits on July 31, 2017. (Exh. 3). The Appellant/Provider received a transfer of appeal rights from the Enrollee/Beneficiary. The amount in controversy meets the jurisdictional amount; therefore, there is jurisdiction to hear this case.

An Administrative Law Judge ("ALJ") hearing was conducted by telephone from Irvine, CA, on September 12, 2017. At the hearing, the Appellant/Provider was represented by Dan McCoy. James Fellingner represented the Health Plan. All exhibits in the Exhibit List ((1-4) were admitted in the record.

Issues

Whether Priority Health is required to cover an electrical stimulation device (Optune) used for cancer treatment (HCPCS E0766) provided by the Appellant/Provider to the Enrollee/Beneficiary?

Facts

The record indicates the Enrollee/Beneficiary requested Priority Health to pre-approve coverage for Optune treatments for diagnosis C718 (malignant neoplasm of the brain). The Optune treatments had previously been approved by Priority Health beginning in April of 2016. A total of 12 treatments were approved from April of 2016 to February of 2017. When a request for additional treatments was received in May of 2017, the request was denied based on LCD L34823 that had an effective date of January 1, 2017, but the original LCD which contains the same language and same policy articles had an effective date of October 1, 2015.

The Enrollee/Beneficiary's progress note dated April 19, 2017 stated that at the time of request the Enrollee/Beneficiary was 57 year old female with a pre-existing seizure disorder since 2000 and an MVA with closed head injury in 2012 with residual expressive aphasia and right hemiparesis. On March 2, 2016, the Enrollee/Beneficiary's MRI revealed a 5.6 x 4.3 x 4.2 cm peripherally enhancing partially cystic/necrotic mass with associated hemorrhage and calcification in the left frontal/temporal lobe with local mass effect and a 7 mm rightward midline shift and leptomeningeal enhancement over the left temporal convexity. Left frontal-temporal craniotomy was performed on March 2, 2016 by Dr. Keltkar with a subtotal resection. Pathology showed a WHO grade 4 glioblastoma with an oligodendroglial component. Postoperative brain MRI showed postsurgical changes with irregular enhancement identified along the medial margin of the mass within the left temporal and parietal lobes compatible with residual neoplasm and partial effacement of the left lateral ventricle and vasogenic edema. The Enrollee/Beneficiary was started on Optune in April 2016 and wore it about 16 hours per day along with several cycles Tomodar therapy. (Exh. 2, pg. 1)

The evidence in the record indicates that Optune is a portable, wearable medical device that delivers TTFT to a targeted tumor. On April 8, 2011, the FDA approved TTFT for treatment of adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme, following histologically or radiologically-confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy and as an alternative to standard medical therapy for glioblastoma multiforme after surgical and radiation options have been exhausted. (Exh. 1, pg. 63)

At the hearing, the Appellant/Provider's representative stated that approximately one hundred medical insurance payer entities now approve coverage for Optune and that it has been approved by several ALJ decisions. The Appellant/Provider's representative also stated that the revised LCD applicable here, which has been used by the Health Plan to deny the continued use of Optune contains only outdated citations to authorities which have not been updated and do not

incorporate the recent successful clinical trials and studies Optune has had since the LCD was first published. The Appellant/Provider's representative also noted that Optune is FDA approved. (Hearing CD; See Exh. 1 at 50-203 for some noted clinical trial summaries and results from 2015).

The Health Plan's representative argued that the applicable LCD should be given deference and that it should apply in this case. The Health Plan's representative speculated that the prior coverage of Optune for the Enrollee/Beneficiary was most likely in error even though the prior LCD contained the same language as the current LCD.

The record included a letter of medical necessity from the Enrollee/Beneficiary's physician, Dr. M.D., who maintained that Optune treatments in combination with temozolomide is the most appropriate option for her at the present time based upon her orphan disease status, limited treatment options and the recently published peer review data from 2015 showing superiority of adding Optune to temozolomide. (Exh. 1, pgs. 31-32)

The record includes a copy of Enrollee/Beneficiary's Plan Evidence of Coverage (Exh. 1 pgs. 247-589)

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an adverse organization determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) § 1859(g)(5); see 42 C.F.R. § 422.600. The request for hearing is timely filed if filed within 60 days of the date of notice of a reconsidered determination. 42 C.F.R. § 422.602.

In implementing this statutory directive, the Secretary delegated authority to administer the nationwide hearings and appeals system for the Medicare program to the Office of Medicare Hearings and Appeals (OMHA). See 70 Fed. Reg. 36386, 36387 (June 23, 2005). ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *Id.*

B. Scope of Review

Medicare Advantage Organization determinations and appeals are governed by the regulations in 42 C.F.R. §§ 422.560 through 422.626. Unless otherwise noted, the ALJ hearing procedures set forth in 42 C.F.R. §§ 405.1000 through 405.1064 apply to Medicare Advantage appeals, to the extent they are appropriate. 42 C.F.R. § 422.562(d).

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the Appellant's favor. 42 C.F.R. § 405.1032(a). However, if evidence presented before the hearing causes the ALJ to

question a favorable portion of the determination, he or she may notify the parties before the hearing and may consider it an issue at the hearing. *Id.*

C. Standard of Review

OMHA is staffed with ALJs who conduct *de novo* hearings. 42 C.F.R. § 405.1000(d). A *de novo* review means the ALJ reviews the evidence without regard to the findings in the prior determinations on the claim and makes an independent assessment based on the evidence and the controlling laws. However, the burden of proving each element of a Medicare claim lies with the appellant and is satisfied by submitting sufficient evidence in accordance with Medicare rules. *See e.g.*, Act §§ 1814(a)(1), 1815(b), and 1833(e); *see also* 42 C.F.R. §§ 424.5(a)(6), 405.1018, 405.1028, and 405.1030.

II. Principles of Law

A. Statutes and Regulations

Eligibility for Medicare benefits is determined under Title XVIII of the Act, 42 U.S.C. § 1801 et seq., and federal regulations set forth in Title 42 of the Code of Federal Regulations.

The Medicare Part C program establishes standards and sets forth the requirements, limitations, and procedures for Medicare services furnished, or paid for, by Medicare Advantage (MA) organizations through MA plans. *See* Act § 1851 *et seq.*; *see also* 42 C.F.R. § 422.1(b) *et seq.* A person is eligible to enroll in Part C if s/he is entitled to Medicare Part A and enrolled in Part B; has not been medically determined to have end-stage renal disease; and meets the applicable residency requirements. *See* Act § 1851(a)(3) – (b); *see also* 42 C.F.R. § 422.50(a).

Generally, an MA plan must provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Parts A and B of Medicare (Original Medicare) and available to beneficiaries residing in the plan's service area. *See* Act § 1852(a)(1); *see also* 42 C.F.R. § 422.101(a). The MAO must disclose the benefits offered under the MA plan, including applicable conditions and limitations, premiums and cost sharing (such as copayments, deductibles, and coinsurance), and any other conditions associated with receipt or use of benefits. 42 C.F.R. § 422.111.

According to section 1862(a)(1)(A) of the Act, no payment may be made under Original Medicare for any expenses incurred for items or services that are “not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” *See* 42 U.S.C. § 1395y(a)(1)(A); *see also* 42 C.F.R. § 411.15(k)(1).

B. Policy and Guidance

Section 1871(a)(2) of the Act provides that no rule, requirement or statement of policy, other than a national coverage determination (NCD), can establish or change a substantive legal standard governing the scope of the benefits or payment for services under the Medicare program unless promulgated as a regulation by CMS. NCDs promulgated by the Secretary of HHS under the authority of Section 1862(a)(1) of the Act dictate the criteria under which Medicare covers specified services, procedures or supplies. NCDs are binding upon ALJs. 42 C.F.R.

§ 405.1060(a)(4); *see* 42 C.F.R. § 405.1060(b)(1) (“An ALJ may not disregard, set aside or otherwise review an NCD”).

Although not subject to the force and effect of law, CMS and its contractors issue policies, manuals and guidelines that describe criteria for coverage of selected types of medical items and services in the form of manuals and local coverage determinations (LCDs). **42 C.F.R. § 405.1062 states that an ALJ is not bound by LCDs or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. If an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed. An ALJ decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.** (emphasis added).

LCD L34823 entitled “Tumor Treatment Field Therapy (TTFT)” provides that TTFT (E0766) will be denied as not reasonable and necessary.

The undersigned notes that the LCD contains a blanket citation to authorities for support but provides no rationale, discussion or criteria upon which exceptions can be made within the context of the LCD, or upon which the LCD is based. Moreover, it does not discuss what authorities it specifically relies upon, nor what the authorities purport to state.

Policy Article A52711 provides additional guidance for TTFT, and seems to provide some inconsistent analysis with the LCD, as follows:

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. “reasonable and necessary”). **Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)).** In order for a beneficiary’s equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Code E0766 is in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories. Separate billing of supplies and/or accessories will be denied as unbundling.

Code A4555 is not valid for billing to Medicare. If code A4555 is billed, it will be denied as an invalid code.

CODING GUIDELINES

Code E0766 describes devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers.

This code is inclusive of all associated supplies necessary for the effective use of code E0766 including, but not limited to, transducers/surface electrodes, lead wires, adhesive patches, connectors, conductive gel and skin preps.

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

The accompanying Policy Article A52711 therefore establishes that TTFT is categorized under the Durable Medical Equipment benefit. The article explains that code E0766 describes “devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers.” The article further states that TTFT devices are in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories. While it defers to any applicable LCD it seems to confirm categorically that in particular cases such treatments should be found to be medically reasonable and necessary. Additionally, it anticipates that any applicable LCD will provide eligibility criteria.

Analysis

After careful consideration of the evidence and arguments presented, the undersigned ALJ finds that the Optune treatment is reasonable and necessary for purposes of coverage under Medicare for the Enrollee/Beneficiary.

An MA plan must provide an enrollee with coverage for all items and services covered by Medicare Part A (except hospice services) and Part B that are available to beneficiaries in the plan's service area. See Section 1852 (a) (1) of the Social Security Act (Act); 42 C. F. R. §§ 422.100 (c) (1); 422.101 (a). An MA plan must comply with National Coverage Determinations (NCDs), general coverage guidelines included in original Medicare manuals and instructions, and written coverage decisions of local Medicare contractors with jurisdiction over claims in the geographic area in which services are covered under the MA plan. 42 C.F.R. § 422.101(b). Therefore, if Medicare does not cover an item or service, unless the plan covers the item or service through supplemental benefits, the Plan is not required to cover the item or service at issue. See 42 C.F.R. § 422.102.

An LCD is program guidance developed by a Medicare contractor and is applicable only in that contractor's service area. An ALJ is not bound by program guidance such as LCDs, program memoranda or manual instructions. However, an ALJ must give such policies substantial deference if applicable in a particular case. 42 C.F.R. § 405.1062(a). If an ALJ declines to follow a policy in a particular case, the rationale for not following that policy must be explained. 42 C.F.R. § 405.1062(b).

As mentioned above, the Appellant/Provider argues that approximately one hundred medical insurance payer entities approve coverage of Optune and many ALJ have approved coverage. The Appellant/Provider also argues that the applicable LCD and accompanying Policy Article contain only citations to outdated clinical studies and do not incorporate more successful clinical trials and studies showing the success of the Optune treatment. As to the first argument that many insurance companies and ALJs have approved coverage of the Optune treatment, the undersigned ALJ finds this argument irrelevant. The fact that many insurance companies and ALJs have approved coverage does not affect the independent judgment of the undersigned ALJ since neither insurance companies nor other ALJs decisions to coverage the Optune treatment have precedential effect. However, the undersigned ALJ does find the Appellant/Provider's argument regarding updated peer review articles and clinical trials/studies to be persuasive.

In this case, the Contractor with jurisdiction over the Enrollee/Beneficiary's geographical area has issued LCD L34823, effective October 1, 2015; with as subsequent revision effective January 1, 2017 for provider education/guidance. The LCD is entitled "Tumor Treatment Field Therapy (TTFT)" and states explicitly that such treatment, billed under HCPCS code E0766, "will be denied as not reasonable and necessary." The LCD also includes a list of sources on which the determination evidently was based. The contractor also issued an accompanying Policy Article, now identified as A52711, which provides "non-medical necessity coverage and payment rules." The article explains that "Code E0766 describes devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers." A52711. The article further states that "[TTFT] devices are covered under the Durable Medical Equipment benefit (Social Security Act § 1861(s) (6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the Local Coverage Determination must be met." Id . Therefore, while the device at issue may be categorized under the Durable Medical Equipment benefit, the LCD has made clear that, at this time, it is not considered reasonable and necessary under any circumstance.

Pursuant to 42 C.F.R. § 405.1062, Medicare regulations permit an ALJ to decline to follow a local coverage policy in individual cases if he/she sets forth specific reasons. After carefully weighing all of the factors in this case, the undersigned ALJ declines follow the applicable LCD L34823 in this particular case.

The undersigned ALJ agrees with the Appellant/Provider's contention that the citations and authorities relied upon in LCD L34823 are outdated and do not necessarily reflect the consensus of the medical community. The evidence in the record indicates that the Optune treatment has increased the Enrollee/Beneficiary's life span and is more likely than not going to continue to increase her life span survival by several months or more.

The undersigned ALJ notes that the prior LCD contained the same language as the current LCD at the time the Optune treatment was first approved by the Health Plan in April 2016. At the time, the Health Plan approved Optune treatment instead of denying it as not medically reasonable and necessary based on the LCD. Based upon the approval of the Optune treatment last year, the Enrollee/Beneficiary was able to greatly benefit and rely on the treatment. Since the Enrollee/Beneficiary's Optune treatment was successful according to her treating physician, the Enrollee/Beneficiary was planning on continuing the Optune treatment this year. However, as noted, the Health Plan denied coverage of the Optune treatment this year. Although the undersigned ALJ acknowledges that there is no equitable relief, nevertheless, she has been

relying on the Optune treatment to treat her medical condition. The undersigned ALJ finds this as an additional factor in declining to follow the applicable LCD in this case. As already discussed above, the applicable LCD L34823 does not consider or address recent breakthrough results or general acceptance consensus from the medical community. For these reasons, the undersigned ALJ declines to follow the applicable LCD in this case.

The undersigned ALJ finds that the TTFT device known as Optune is medically reasonable and necessary for the Enrollee/Beneficiary. Priority Health must provide coverage for the TTFT at issue. The medical record contains sufficient documentation of the Enrollee/Beneficiary's medical diagnosis of malignant neoplasm of the brain to substantiate the medical reasonableness and necessity for the Optune treatment at issue, satisfying Medicare rules and regulations.

Conclusions of Law

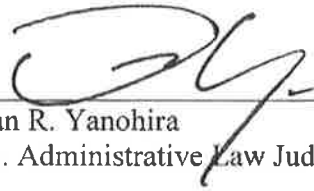
1. Based on the totality of the evidence of record, the undersigned ALJ finds that Priority Health is required to grant the Enrollee/Beneficiary's prior approval request for the TTFT device at issue. This decision is made in accordance with the Medicare Part C provisions of Title XVIII of the Social Security Act, Medicare guidelines, and the terms of the health plan.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated: OCT 24 2017



Dean R. Yanohira
U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Cleveland, Ohio

Appeal of:	ALJ Appeal No.: 1-6764222904
Enrollee:	Medicare Part C
HICN: *****3156A	Before: Richard J. Zettel U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record and at the hearing, a **FULLY FAVORABLE** decision is entered for the Appellant/Enrollee.

Procedural History

The Appellant is an enrollee of a Medicare Part C Advantage Plan, Capital Health Plan Retiree Advantage (HMO) (“the MA plan”) (Exhibit 1). The Appellant sought pre-approval for tumor treatment field therapy (TTFT) from the MA plan, which was denied (Exhibit 1). A Qualified Independent Contractor (QIC), Maximus Federal Services, issued an unfavorable reconsideration decision on June 27, 2017 (Exhibit 1, page 11). The QIC found that TTFT was not medically reasonable and necessary under Medicare rules. The QIC concluded that the MA plan was not required to provide pre-approval for TTFT for the Appellant.

The Appellant submitted a timely request for an Administrative Law Judge (ALJ) hearing to the Office of Medicare Hearings and Appeals (OMHA) on September 11, 2017 (Exhibit 3, page 2). The amount in controversy meets the jurisdictional requirement for a hearing before OMHA (Exhibit 1).

A telephonic hearing before the ALJ was held on November 29, 2017, in Cleveland, Ohio. [redacted] the Appellant, [redacted] the Appellant’s spouse, [redacted] the Appellant’s daughter, and David Tran, MD, treating physician, appeared on behalf of the Appellant and testified under oath. Shannon Fisher, Case Manager at Novocure and appointed representative, and Justin Kelly, RN, Sr. Director of Health Policy and Payment at Novocure, appeared on behalf of the Appellant and testified under oath. Stephanie Hales, Esq. appeared on behalf of the Appellant and Novocure. Anne Duncan, RN, Grievance and Appeals, Nancy Van Vessem, MD, Clinical Medical Officer, Suzie Humphries, Appeals Manager, and Moritz Dehler,

MD, Associate Medical Director, appeared on behalf of the MA plan and testified under oath. Exhibits 1-4 were admitted into the record.

Issues

The issue is whether the MA plan is required to pre-approval to the Appellant under Part C of Title XVIII of the Social Security Act for TTFT.

Findings of Fact

The attached Exhibit List is incorporated into this Decision by reference. The following facts are established by the preponderance of the evidence.

1. The Appellant is an enrollee of a Medicare Part C Advantage Plan, Capital Health Plan Retiree Advantage (HMO) ("the MA plan") (Exhibit 1). The Appellant seeks pre-approval for TTFT (also known as "Optune therapy").
2. In April of 2016, the Appellant presented with speech difficulties and a new onset of seizures (Exhibit 2, page 4). Neural imaging reported a left temporal brain mass, which was presumed to be brain metastasis due to a recent breast cancer diagnosis. She received treatment, including stereotactic radiosurgery and MR-guided laser ablation.
3. In early March of 2017, the Appellant returned to her physician with two week history progressively worsening speech as well as visual difficulty. *Id.* Neural imaging was concerning for worsening disease.
4. On March 10, 2017, a craniotomy with gross total resection of the mass was performed, which revealed glioblastoma, WHO grade IV with IDH1 wild type, ATRX wild type. *Id.*
5. From April 10, 2017, through May 22, 2017, the Appellant received definite radiation with concurrent temozolomide (*Id.* and Exhibit 2, page 6).
6. On April 17, 2017, the Appellant reported feeling better. *Id.* She had a Karnofsky performance score of 70%.
7. On May 22, 2017, the Appellant reported that she did not take her last five doses of temozolomide due to pancytopenia requiring platelet transfusions. *Id.* She had a Karnofsky performance score of 70%.
8. The plan included the following: maintenance temozolomide; Optune therapy; physical, occupational, and speech therapy; and follow-up brain MR scan. *Id.*
9. A prescription for Optune was signed by Dr. Tran on May 23, 2017, to treat glioblastoma (Exhibit 2, page 3).
10. The Appellant is unable to tolerate further chemotherapy treatment (Hearing testimony; Dr. Tran).

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) § 1869(b)(1)(A).

In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council.

A hearing before an ALJ is only available if the remaining amount in controversy is \$160. 81 Fed. Reg. 65651 (Sept. 23, 2016) (setting the 2017 amount in controversy threshold amount at \$160). The request for hearing is timely if filed within sixty days after receipt of the QIC's reconsideration decision. *See*, 42 C.F.R. § 405.1002.

B. Scope of Review

“The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. (For purposes of this provision, the term “party” does not include a representative of CMS or one of its contractors that may be participating in the hearing.) However, if evidence presented before the hearing causes the ALJ to question a favorable portion of the determination, he or she notifies the parties before the hearing and may consider it an issue at the hearing.” *See* 42 C.F.R. § 405.1032(a).

C. Standard of Review

Pursuant to § 557 of the Administrative Procedure Act (“APA”), an ALJ qualified and appointed pursuant to the APA acts as an independent finder of fact in conducting a hearing pursuant to § 1869 of the Act. The ALJ conducts a de novo review and issues a decision based on the hearing record. 42 C.F.R. § 405.1000(d).

II. Principles of Law

A. Medicare Law, Regulations, and Local Policy

The Medicare program is set forth in Title XVIII of the Social Security Act (“Act”). Under Title II of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the Medicare Advantage (MA) program was announced as a replacement to the Medicare + Choice (M+C) managed care program. An MA Plan must provide the services currently available under Medicare Parts A and B, and may provide additional services if specified in its policy. 42 C.F.R. § 422.100(a). The MA plan at issue in this case is Capital Health Plan Retiree Advantage (HMO).

Pursuant to 42 C.F.R. § 422.101, while enrolled in a MA plan, an enrollee is entitled to and restricted by the limitations and conditions of that program with respect to Medicare coverage and reimbursement. In turn, the MA plan must make available to an enrollee, or provide reimbursement for, at least all services covered under Part A and Part B of Medicare.

Items and services that are “not reasonable and necessary” for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member are specifically excluded from Medicare coverage pursuant to §1862(a)(1)(A) of the Act. *See also*, 42 CFR §411.15(k)(1).

B. The MA Plan

The MA plan Evidence of Coverage (EOC) provides coverage for service covered by Medicare (Exhibit 1).

C . CMS Guidance and Local Policy

A Local Coverage Determination (LCD), as established by § 522 of the Benefits Improvement and Protection Act, is a decision by a fiscal intermediary or carrier whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with § 1862(a)(1)(A) of the Act (i.e., a determination as to whether the service is reasonable and necessary). CGS Administrators and Noridian Healthcare Solutions, LLC issued Local Coverage Determination: Tumor Treatment Field Therapy (LCD L34823) (Jan. 2017), which provides in relevant part as follows: Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

Analysis

The QIC found that TTFT was not medically reasonable and necessary under Medicare rules. The QIC concluded that the MA plan was not required to provide pre-approval for TTFT for the Appellant. The ALJ disagrees with the findings of the QIC and determines that the Appellant is entitled to pre-approval under Part C of Medicare for TTFT.

The QIC relied upon LCD L34823 to deny pre-approval for TTFT for the Appellant. LCD L34823 provides that TTFT will be denied as not reasonable and necessary. Pursuant to 42 C.F.R. § 405.1062(a), an ALJ must give substantial deference to local coverage determinations. If an ALJ declines to follow a local coverage determination, the ALJ must explain the reason why the policy was not followed in accordance with 42 C.F.R. § 405.1062(b). After careful consideration of the record and hearing testimony, the ALJ has decided to depart from LCD L34823 under the specific facts of this appeal.

First, the ALJ finds that LCD L34823 fails to identify any justification for the denial of all TTFT as not reasonable and necessary. Dr. Tran testified at the hearing and stated in his written appeal documentation that the Food and Drug Administration has approved Optune to treat glioblastoma, which is the most common form of brain cancer in the United States. In addition, Dr. Tran pointed out that many payers are covering TTFT based on individual medical necessity review as well as published medical policy.

Second, the ALJ finds that the documentation and hearing testimony support that TTFT is medically reasonable and necessary to treat the Appellant. In April of 2016, the Appellant presented with speech difficulties and a new onset of seizures. Neural imaging reported a left temporal brain mass, which was presumed to be brain metastasis due to a recent breast cancer diagnosis. She received treatment, including stereotactic radiosurgery and MR-guided laser ablation. In early March of 2017, the Appellant returned to her physician with two week history progressively worsening speech as well as visual difficulty. Neural imaging was concerning for worsening disease.

On March 10, 2017, a craniotomy with gross total resection of the mass was performed, which revealed glioblastoma, WHO grade IV with IDH1 wild type, ATRX wild type. From April 10, 2017, through May 22, 2017, the Appellant received definite radiation with concurrent temozolomide. On April 17, 2017, the Appellant reported feeling better. She had a Karnofsky performance score of 70%. On May 22, 2017, the Appellant reported that she did not take her last five doses of temozolomide due to pancytopenia requiring platelet transfusions. She continued to have Karnofsky performance score of 70%. The plan included the following: maintenance temozolomide; Optune therapy; physical, occupational, and speech therapy; and follow-up brain MR scan. A prescription for Optune was signed by Dr. Tran on May 23, 2017, to treat glioblastoma. Despite the initial treatment plan, the Appellant is unable to tolerate further chemotherapy treatment. Dr. Tran and Ms. Prosser testified that the TTFT resulted in improvement for the Appellant.

In sum, the Appellant underwent a craniotomy with gross total resection of a brain mass resulting in a finding of glioblastoma, WHO grade IV. She was treated with definite radiation with concurrent temozolomide. She had Karnofsky performance score of 70%. She has been undergoing TTFT with improvement and has no other treatment options at this time. Based on the foregoing, the ALJ finds that the TTFT is medically reasonable and necessary for the Appellant to treat her glioblastoma. The ALJ concludes that the MA plan is required to provide pre-approval under the MA plan for TTFT for the Appellant.

Conclusions of Law

The ALJ concludes that the MA plan is required to provide pre-approval for TTFT for the Appellant under Part C of Title XVIII of the Act. The ALJ notes that the appeal before him is for pre-approval only, and therefore, the decision applies only to any further TTFT required for the Appellant.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

Dated: 12/11/2017

SO ORDERED.


Richard J. Zettel

U.S. Administrative Law Judge

Enclosures: Form OMHA-156, *List of Exhibits*



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Cleveland, Ohio

Appeal of:	ALJ Appeal No.: 1-7770746813
Beneficiary:	Medicare Part B
HICN:	Before: Richard J. Zettel U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record and at the hearing, a **FULLY FAVORABLE** decision is entered for the Appellant,

Procedural History

The Appellant was treated with electronic stimulation cancer treatment, tumor treatment field therapy (CPT code E0766) (hereinafter referred to as "TTFT") (also known as Optune) on July 19, 2017, August 19, 2017, September 19, 2017, and October 19, 2017 (Exhibit 2). A claim for the TTFT was submitted to a Part B Durable Medical Equipment Medicare Administrative Contractor (DME MAC), which was denied initially and upon redetermination (Exhibit 1). On June 15, 2018, a Qualified Independent Contractor (QIC), C2C Solutions, Inc., issued an unfavorable reconsideration decision (Exhibit 1, page 1). The QIC determined that payment could not be paid because the published studies in the medical literature did not clearly document the effectiveness of the device. The QIC held the Provider liable for the non-covered charges.

The Appellant submitted a timely request for an Administrative Law Judge (ALJ) hearing to the Office of Medicare Hearings and Appeals (OMHA) on July 27, 2018 (Exhibit 3, page 1). The amount in controversy meets the jurisdictional requirement for a hearing before OMHA (Exhibit 1).

A telephonic hearing before the ALJ was held on October 16, 2018, in Cleveland, Ohio. Debra Parrish, Esq. appeared on behalf of the Appellant. Daniel McCoy, Case Management Manager, and Julie Miles, RN, Clinical Appeals Specialist, appeared on behalf of the Appellant and testified under oath. Exhibits 1-4 were admitted into the record.

Issues

The ALJ is asked to decide whether the TTFT provided to the Appellant on multiple dates of service is reimbursable under Part B of Title XVIII of the Social Security Act, and if not, who is liable for the non-covered charges.

Findings of Fact

The attached Exhibit List is incorporated into this Decision by reference. The following facts are established by the preponderance of the evidence.

1. The Appellant was treated with electronic stimulation cancer treatment, tumor treatment field therapy (CPT code E0766) (hereinafter referred to as "TTFT") (also known as Optune) on July 19, 2017, August 19, 2017, September 19, 2017, and October 19, 2017 (Exhibit 2).
2. The Appellant was 75 years-old during the dates of service at issue (Exhibit 2, page 5).
3. A cancer center follow-up note is dated April 20, 2017 (Exhibit 2, page 7).
4. The Appellant had diagnoses of anaplastic astrocytoma, WHO grade III and prostate cancer status post prostatectomy (*Id.* and Exhibit 2, page 15).
5. The Appellant was seen as an inpatient on April 5, 2017, presenting with a seizure (Exhibit 2, page 7).
6. An MRI of the brain showed a 7-mm left temporal lobe lesion with surrounding vasogenic edema. *Id.*
7. On April 7, 2017, the Appellant underwent a maximal safe resection. *Id.* Pathology confirmed astrocytoma WHO grade II.
8. The Appellant was discharged from the hospital on April 10, 2017. *Id.*
9. The plan was for hypofractionated course of 40.05 Gy in 15 fractions. *Id.*
10. A cancer center follow-up note is dated June 23, 2017 (Exhibit 2, page 5).
11. The Appellant was status post maximal safe resection with no residual tumors seen on postoperative MRI. *Id.* He was treated with radiation therapy on May 22, 2017.
12. The plan was to obtain a MRI of the brain in a couple of weeks and review the results. *Id.*
13. A prescription for Optune was signed by _____ MD on June 23, 2017, to treat malignant neoplasm of the temporal lobe (Exhibit 2, page 1).
14. The record includes documentation from the Appellant's hospital stay (Exhibit 2, pages 9-23).

15. Optune is FDA approved for recurrent and newly diagnosed glioblastoma multiforme brain tumors (Exhibit 4, page 6; Hearing testimony).
16. TTFT disrupts and corrupts the division of cancer cells and leads to the death of such cells (Exhibit 3, page 1).
17. Peer-reviewed literature shows the improved clinical outcome of patients who receive TTFT for their glioblastoma (Exhibit 1; Hearing testimony).
18. TTFT for glioblastoma is included in the National Comprehensive Cancer Network guidelines. *Id.*

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) § 1869(b)(1)(A).

In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMIHA. The ALJs within OMIHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council.

A hearing before an ALJ is only available if the remaining amount in controversy is \$160. 82 Fed. Reg. 45592 (Sept. 29, 2017) (setting the 2018 amount in controversy threshold amount at \$160). The request for hearing is timely if filed within sixty days after receipt of the QIC's reconsideration decision. *See*, 42 C.F.R. § 405.1002.

B. Scope of Review

"The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. (For purposes of this provision, the term "party" does not include a representative of CMS or one of its contractors that may be participating in the hearing.) However, if evidence presented before the hearing causes the ALJ to question a favorable portion of the determination, he or she notifies the parties before the hearing and may consider it an issue at the hearing." *See*, 42 C.F.R. § 405.1032(a).

C. Standard of Review

Pursuant to § 557 of the Administrative Procedure Act ("APA"), an ALJ qualified and appointed pursuant to the APA acts as an independent finder of fact in conducting a hearing pursuant to

§ 1869 of the Act. The ALJ conducts a de novo review and issues a decision based on the hearing record. 42 C.F.R. § 405.1000(d).

II. Principles of Law

A. Social Security Act and Code of Federal Regulations

The Medicare program, Title XVIII of the Act, is administered through the Centers for Medicare and Medicaid Services, a component of the United States Department of Health and Human Services (HHS). Under the authority of Section 1842(a) (1) (A) of the Act, the Secretary of HHS is authorized to enter into contracts with private entities for the day-to-day operations of the program. For claims for durable medical equipment, prosthetics, orthotics, and supplies, DME MACs administer the processing of the claims.

Part B of Title XVIII of the Act, the Supplementary Medical Insurance program, provides coverage for a variety of medical services and supplies furnished by physicians, or by others in connection with physicians' services, for outpatient hospital services, and for a number of other specific health-related items and services. Individuals participate voluntarily in the Medicare Part B program and pay a monthly premium.

Section 1862(a)(1) of the Act excludes Medicare payment for services which "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member".

Section 1834(a)(15)(C) of the Act provides that carriers shall, at the request of a supplier or beneficiary, determine in advance of delivery of an item whether payment for the item may not be made because the item is not covered if the item is a customized item, the patient to whom the item is to be furnished, or the supplier, requests that such advance determination be made, and the item is not an inexpensive item as specified by the Secretary.

Section 1832(a) of the Act states, in pertinent part: The benefits provided to an individual by the insurance program established by this part shall consist of

- (1) entitlement to have payment made to him or on his behalf (subject to the provisions of this part) for medical or other health services...

Section 1861(s) of the Act provides that the term "medical and other health services" includes durable medical equipment. 42 CFR § 414.202 defines durable medical equipment as equipment furnished by a supplier or a home health agency that-

- (1) can withstand repeated use;
- (2) is primarily and customarily used to serve a medical purpose;
- (3) generally is not useful to an individual in the absence of an illness or injury;
- and
- (4) is appropriate for use in the home.

42 CFR § 410.38(a) provides in pertinent part as follows regarding the scope and conditions of durable medical equipment:

Medicare Part B pays for the rental or purchase of durable medical equipment, including iron lungs, oxygen tents, hospital beds, and wheelchairs, if the equipment is used in the patient's home or in an institution that is used as a home.

B. CMS Manual System and Local Policy

The manuals issued by the Centers for Medicare and Medicaid Services (CMS) administering the Medicare program also are considered. Although not binding on the ALJ, the respective manuals provide guidance in the administration of the Medicare program. In *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87, 102 (1995), the United States Supreme Court concluded that an agency manual section is a valid interpretive rule and that it is reasonable for the agency to follow it. CMS, *Medicare Benefit Policy Manual (MBPM) (Internet-Only Manual Publ'n 100-2)* ch. 15, § 110, provides general coverage guidelines for durable medical equipment.

A Local Coverage Determination (LCD), as established by § 522 of the Benefits Improvement and Protection Act, is a decision by a fiscal intermediary or carrier whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with § 1862(a)(1)(A) of the Act (i.e., a determination as to whether the service is reasonable and necessary). CGS Administrators and Noridian Healthcare Solutions, LLC issued Local Coverage Determination: Tumor Treatment Field Therapy (LCD L34823) (Jan. 2017), which provides in relevant part as follows: Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

Analysis

The QIC determined that payment could not be paid because the published studies in the medical literature did not clearly document the effectiveness of the device. The QIC held the Provider liable for the non-covered charges. The ALJ disagrees with the findings of the QIC and determines that the TTFT provided to the Appellant is covered under Part B of Medicare.

Medicare is a defined benefit program, which means that it does not cover all available medical services and supplies. Medicare coverage is limited to those medical services and supplies identified by Congress, and by the Secretary of Health and Human Services and CMS in implementing Congressional directives. Medicare does not cover medical services that are not medically reasonable and necessary under § 1862(a)(1) of Act.

The QIC relied upon LCD L34823 to deny coverage for the TTFT for the Appellant. LCD L34823 provides that TTFT will be denied as not reasonable and necessary. Pursuant to 42 C.F.R. § 405.1062(a), an ALJ must give substantial deference to local coverage determinations. If an ALJ declines to follow a local coverage determination, the ALJ must explain the reason why the policy was not followed in accordance with 42 C.F.R. § 405.1062(b). After careful consideration of the record and hearing testimony, the ALJ has decided to depart from LCD L34823 under the specific facts of this appeal.

First, the ALJ finds that LCD L34823 fails to identify any justification for the denial of all TTFT as not reasonable and necessary. The Appellant provided documentation that LCD L23823 is currently being written to establish coverage guidelines for TTFT. In addition, the record and hearing testimony support that TTFT is an effective treatment of glioblastoma. Optune is FDA approved for recurrent and newly diagnosed glioblastoma multiforme brain tumors. TTFT disrupts and corrupts the division of cancer cells and leads to the death of such cells. Peer-reviewed literature shows the improved clinical outcome of patients who receive TTFT for their glioblastoma. TTFT for glioblastoma is included in the National Comprehensive Cancer Network guidelines. Finally, the Appellant pointed out that many payers are covering TTFT based on individual medical necessity review as well as published medical policy.

Second, the ALJ finds that the documentation and hearing testimony support that TTFT is medically reasonable and necessary to treat the Appellant. The Appellant was 75 years-old during the dates of service at issue. A cancer center follow-up note is dated April 20, 2017. The Appellant had diagnoses of anaplastic astrocytoma, WHO grade III and prostate cancer status post prostatectomy. He was seen as an inpatient on April 5, 2017, presenting with a seizure. An MRI of the brain showed a 7-mm left temporal lobe lesion with surrounding vasogenic edema. On April 7, 2017, the Appellant underwent a maximal safe resection. Pathology confirmed astrocytoma WHO grade II. The Appellant was discharged on April 10, 2017, and the plan was for hypofractionated course of 40.05 Gy in 15 fractions.

A cancer center follow-up note is dated June 23, 2017. The Appellant was status post maximal safe resection with no residual tumors seen on postoperative MRI. He was treated with radiation therapy on May 22, 2017. The plan was to obtain a MRI of the brain in a couple of weeks and review the results. A prescription for Optune was signed by Norleena Gullett, MD on June 23, 2017, to treat malignant neoplasm of the temporal lobe.

Based on the foregoing, the TTFT provided to the Appellant on the dates of service was medically reasonable and necessary. The TTFT provided to the Appellant on July 19, 2017, August 19, 2017, September 19, 2017, and October 19, 2017, is reimbursable under Part B of Medicare.

Conclusions of Law

The ALJ concludes that the TTFT provided to the Appellant on multiple dates of service was medically reasonable and necessary. Accordingly, the ALJ finds that the TTFT (E0766) provided to the Appellant on July 19, 2017, August 19, 2017, September 19, 2017, and October 19, 2017, is reimbursable under Part B of Title XVIII of the Act.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

Dated: 10/30/18

SO ORDERED.


Richard J. Zettel
U.S. Administrative Law Judge

Enclosures:

Form OMHA-156, *List of Exhibits*



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Cleveland, Ohio

Appeal of:

OMHA Appeal No.: 1-7868456646

Beneficiary:

Medicare: Part B

Medicare No.:

Before: Richard J. Zettel
Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record and at the hearing, a **FULLY FAVORABLE** decision is entered for the Appellant.

Procedural History

The Appellant was treated with electronic stimulation cancer treatment, tumor treatment field therapy (CPT code E0766) (hereinafter referred to as "TTFT") (also known as Optune) on September 11, 2017, October 11, 2017, November 11, 2017, December 11, 2017 and January 11, 2018 (Exhibit 2). A claim for the TTFT was submitted to a Part B Durable Medical Equipment Medicare Administrative Contractor (DME MAC), which was denied initially and upon redetermination (Exhibit 1). On August 15, 2018, a Qualified Independent Contractor (QIC), C2C Solutions, Inc., issued an unfavorable reconsideration decision (Exhibit 1, page 1). The QIC determined that payment could not be paid because there was insufficient evidence to quantify the effects of the device for this Beneficiary. The QIC held the Provider liable for the non-covered charges.

The Appellant submitted a timely request for an Administrative Law Judge (ALJ) hearing to the Office of Medicare Hearings and Appeals (OMHA) on September 11, 2018 (Exhibit 3). The amount in controversy meets the jurisdictional requirement for a hearing before OMHA (Exhibit 1).

A telephonic hearing before the ALJ was held on November 6, 2018, in Cleveland, Ohio. Debra Parrish, Esq. appeared on behalf of the Appellant. Daniel McCoy, Case Management Manager, and Julie Miles, RN, Clinical Appeals Specialist, appeared on behalf of the Appellant and testified under oath. Exhibits 1-4 were admitted into the record.

Issues

The ALJ is asked to decide whether the TTFT provided to the Appellant on multiple dates of service is reimbursable under Part B of Title XVIII of the Social Security Act, and if not, who is liable for the non-covered charges.

Findings of Fact

The attached Exhibit List is incorporated into this Decision by reference. The following facts are established by the preponderance of the evidence.

1. The Appellant was treated with electronic stimulation cancer treatment, tumor treatment field therapy (CPT code E0766) (hereinafter referred to as "TTFT") (also known as Optune) on September 11, 2017, October 11, 2017, November 11, 2017, December 11, 2017 and January 11, 2018 (Exhibit 2).
2. The Appellant was 76 years-old during the dates of service at issue. *Id.*
3. The Appellant presented to the hospital on May 8, 2017 with complaints of worsening memory and speech over 2 months prior. His primary physician had referred him to get an MRI of his brain which was completed on May 2, 2017. The MRI revealed a 2.3 x 1.8 cm ring-enhancing mass with vasogenic edema (Exhibit 2, page 21-23).
4. The Appellant underwent a craniotomy on May 4, 2017 (Exhibit 2, page 19-23).
5. The Surgical Pathology Report dated May 11, 2017 reflects a final diagnosis of brain, left frontal tumor, exolsion glioblastoma, small cell features, WHO grade IV (4): IDH1 (R132H) wildtype by immunohistochemistry (Exhibit 2, page 16).
6. An MRI of the brain on May 12, 2017 showed 1) Operative changes with resection cavity in posterior left frontal lobe, 2) small circumscribed focal hemorrhage situated posterior to the resection cavity, 3) Vasogenic edema in superior lateral left frontal lobe, 4) thin subdural hematoma over lateral left cerebral hemisphere, and 5) white matter signal change consistent with microvascular gliosis (Exhibit 2, pages 14-15).
7. The Appellant was prescribed Optune (NovoTTF-100A system) to treat the glioblastoma (Exhibit 2, pages 1-3).
8. The Appellant was billed for the Optune (NOVO-TTF 100A system) (Exhibit 2, page 34-38).
9. Optune is FDA approved for recurrent and newly diagnosed glioblastoma multiforme brain tumors (Exhibit 4, page 10; Hearing testimony).
10. TTFT disrupts and corrupts the division of cancer cells and leads to the death of such cells (Exhibit 3, page 1).

11. Peer-reviewed literature shows the improved clinical outcome of patients who receive TTFT for their glioblastoma (Exhibit 1: Hearing testimony).
12. TTFT for glioblastoma is included in the National Comprehensive Cancer Network guidelines. *Id.*

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) § 1869(b)(1)(A).

In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council.

A hearing before an ALJ is only available if the remaining amount in controversy is \$160. 82 Fed. Reg. 45592 (Sept. 29, 2017) (setting the 2018 amount in controversy threshold amount at \$160). The request for hearing is timely if filed within sixty days after receipt of the QIC's reconsideration decision. *See*, 42 C.F.R. § 405.1002.

B. Scope of Review

"The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. (For purposes of this provision, the term "party" does not include a representative of CMS or one of its contractors that may be participating in the hearing.) However, if evidence presented before the hearing causes the ALJ to question a favorable portion of the determination, he or she notifies the parties before the hearing and may consider it an issue at the hearing." *See*, 42 C.F.R. § 405.1032(a).

C. Standard of Review

Pursuant to § 557 of the Administrative Procedure Act ("APA"), an ALJ qualified and appointed pursuant to the APA acts as an independent finder of fact in conducting a hearing pursuant to § 1869 of the Act. The ALJ conducts a de novo review and issues a decision based on the hearing record. 42 C.F.R. § 405.1000(d).

II. Principles of Law

A. Social Security Act and Code of Federal Regulations

The Medicare program, Title XVIII of the Act, is administered through the Centers for Medicare and Medicaid Services, a component of the United States Department of Health and Human Services (HHS). Under the authority of Section 1842(a) (1) (A) of the Act, the Secretary of HHS is authorized to enter into contracts with private entities for the day-to-day operations of the program. For claims for durable medical equipment, prosthetics, orthotics, and supplies, DME MACs administer the processing of the claims.

Part B of Title XVIII of the Act, the Supplementary Medical Insurance program, provides coverage for a variety of medical services and supplies furnished by physicians, or by others in connection with physicians' services, for outpatient hospital services, and for a number of other specific health-related items and services. Individuals participate voluntarily in the Medicare Part B program and pay a monthly premium.

Section 1862(a)(1) of the Act excludes Medicare payment for services which "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member".

Section 1834(a)(15)(C) of the Act provides that carriers shall, at the request of a supplier or beneficiary, determine in advance of delivery of an item whether payment for the item may not be made because the item is not covered if the item is a customized item, the patient to whom the item is to be furnished, or the supplier, requests that such advance determination be made, and the item is not an inexpensive item as specified by the Secretary.

Section 1832(a) of the Act states, in pertinent part: The benefits provided to an individual by the insurance program established by this part shall consist of

- (1) entitlement to have payment made to him or on his behalf (subject to the provisions of this part) for medical or other health services...

Section 1861(s) of the Act provides that the term "medical and other health services" includes durable medical equipment. 42 CFR § 414.202 defines durable medical equipment as equipment furnished by a supplier or a home health agency that-

- (1) can withstand repeated use;
- (2) is primarily and customarily used to serve a medical purpose;
- (3) generally is not useful to an individual in the absence of an illness or injury;
- and
- (4) is appropriate for use in the home.

42 CFR § 410.38(a) provides in pertinent part as follows regarding the scope and conditions of durable medical equipment:

Medicare Part B pays for the rental or purchase of durable medical equipment, including iron lungs, oxygen tents, hospital beds, and wheelchairs, if the equipment is used in the patient's home or in an institution that is used as a home.

B. CMS Manual System and Local Policy

The manuals issued by the Centers for Medicare and Medicaid Services (CMS) administering the Medicare program also are considered. Although not binding on the ALJ, the respective manuals provide guidance in the administration of the Medicare program. In *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87, 102 (1995), the United States Supreme Court concluded that an agency manual section is a valid interpretive rule and that it is reasonable for the agency to follow it. CMS, *Medicare Benefit Policy Manual (MBPM) (Internet-Only Manual Publ'n 100-2)* ch. 15, § 110, provides general coverage guidelines for durable medical equipment.

A Local Coverage Determination (LCD), as established by § 522 of the Benefits Improvement and Protection Act, is a decision by a fiscal intermediary or carrier whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with § 1862(a)(1)(A) of the Act (i.e., a determination as to whether the service is reasonable and necessary). CGS Administrators and Noridian Healthcare Solutions, LLC issued Local Coverage Determination: Tumor Treatment Field Therapy (LCD L34823) (Jan. 2017), which provides in relevant part as follows: Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

Analysis

The QIC determined that payment could not be paid because there was insufficient evidence to quantify the effects of the device for this Beneficiary. The QIC held the Provider liable for the non-covered charges. The ALJ disagrees with the findings of the QIC and determines that the TTFT provided to the Appellant is covered under Part B of Medicare.

Medicare is a defined benefit program, which means that it does not cover all available medical services and supplies. Medicare coverage is limited to those medical services and supplies identified by Congress, and by the Secretary of Health and Human Services and CMS in implementing Congressional directives. Medicare does not cover medical services that are not medically reasonable and necessary under § 1862(a)(1) of Act.

The QIC relied upon LCD L34823 to deny coverage for the TTFT for the Appellant. LCD L34823 provides that TTFT will be denied as not reasonable and necessary. Pursuant to 42 C.F.R. § 405.1062(a), an ALJ must give substantial deference to local coverage determinations. If an ALJ declines to follow a local coverage determination, the ALJ must explain the reason why the policy was not followed in accordance with 42 C.F.R. § 405.1062(b). After careful consideration of the record and hearing testimony, the ALJ has decided to depart from LCD L34823 under the specific facts of this appeal.

The ALJ finds that LCD L34823 fails to identify any justification for the denial of all TTF as not reasonable and necessary. The Appellant provided documentation that LCD L23823 is currently being written to establish coverage guidelines for TTF. In addition, the record and hearing testimony support that TTF is an effective treatment of glioblastoma. Optune is FDA approved for recurrent and newly diagnosed glioblastoma multiforme brain tumors. TTF disrupts and corrupts the division of cancer cells and leads to the death of such cells. Peer-reviewed literature shows the improved clinical outcome of patients who receive TTF for their glioblastoma. TTF for glioblastoma is included in the National Comprehensive Cancer Network guidelines. Finally, the Appellant pointed out that many payers are covering TTF based on individual medical necessity review as well as published medical policy.

The ALJ further finds that the documentation and hearing testimony support that TTF is medically reasonable and necessary to treat the Appellant. The Appellant was treated with electronic stimulation cancer treatment, tumor treatment field therapy (CPT code E0766) (TTF) (also known as Optune) on September 11, 2017, October 11, 2017, November 11, 2017, December 11, 2017 and January 11, 2018.

The 76 year old Appellant presented to the hospital on May 8, 2017 with complaints of worsening memory and speech over 2 months prior. His primary physician had referred him to get an MRI of his brain which was completed on May 2, 2017. The MRI revealed a 2.3 x 1.8 cm ring-enhancing mass with vasogenic edema. The Appellant underwent a craniotomy on May 4, 2017. The Surgical Pathology Report dated May 11, 2017 reflects a final diagnosis of brain, left frontal tumor, excision – glioblastoma, small cell features, WHO grade IV (4); IDH1 (R132H) wildtype by immunohistochemistry. An MRI of the brain on May 12, 2017 showed Vasogenic edema in superior lateral left frontal lobe, and white matter signal change consistent with microvascular gliosis. The Appellant was prescribed and billed for Optune (NovoTTF-100A system) to treat the glioblastoma.

At the hearing, Ms. Parrish reviewed the Appellant's medical history of glioblastoma, and explained how the TTF at issue was a huge success in the Beneficiary's cancer treatment. She noted the Beneficiary had a life expectancy of ten months and has lived seventeen months so far. She argued the American Medical Association has indicated it is unethical to withhold this treatment because it is so effective. She explained that because the treatment is so effective, the FDA terminated the trials for the treatment early. She noted it is not FDA approved and accepted in all 50 states as a standard of care. Ms. Parrish asserted it is covered by all major carriers and Mr. McCoy confirmed this assertion. Ms. Miles explained that glioblastoma is the most aggressive form of brain cancer. She testified the Beneficiary is still alive and still receiving TTF.

Based on the foregoing, the TTF provided to the Appellant on the dates of service was medically reasonable and necessary. The TTF provided to the Appellant on September 11, 2017, October 11, 2017, November 11, 2017, December 11, 2017 and January 11, 2018, is reimbursable under Part B of Medicare.

Conclusions of Law

The ALJ concludes that the TTF provided to the Appellant on multiple dates of service was medically reasonable and necessary. Accordingly, the ALJ finds that the TTF (E0766) provided

to the Appellant. on September 11, 2017, October 11, 2017, November 11, 2017, December 11, 2017 and January 11, 2018, is reimbursable under Part B of Title XVIII of the Act.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated: 11/29/18


Richard J. Zettel
U.S. Administrative Law Judge



**UNITED STATES DEPARTMENT
OF
HEALTH AND HUMAN SERVICES**
OFFICE OF MEDICARE HEARINGS AND APPEALS
SOUTHERN FIELD OFFICE
Miami, Florida

Appeal of:**ALJ Appeal No.: 1-2669116429****Beneficiary:****Medicare Part C****HICN: XXX-XX-1085A****Before: Lauren Heard
U.S. Administrative Law Judge**

ADMINISTRATIVE LAW JUDGE DECISION AND ORDER

I. SUMMARY OF DECISION

After carefully considering the evidence and arguments presented, a **Favorable** decision is entered for the Beneficiary, ("Beneficiary" or "you") who is also the Appellant. As set forth in more detail herein, the Humana Medicare Employer PPO Medicare Advantage Plan offered by Humana Insurance Company, ("Plan") incorrectly denied coverage for an electrical stimulation device used for cancer treatment, and specifically treatment with the NovoTTF-100APlus Transducer ("Device"). Therefore, the Beneficiary is entitled to Plan benefits for treatment with the Device pursuant to physician orders.

II. PROCEDURAL HISTORY

The Plan received a request for prior authorization for treatment with the Device coded as durable medical equipment ("DME") pursuant to HCPCS Code E0765 (Electrical stimulation device used for cancer treatment, includes all accessories, any type) from the Device Supplier, Novocure, ("Supplier") on behalf of the Beneficiary. The Supplier indicates a willingness to offer a discount off the list price for the device via a negotiated letter of agreement for in network benefits. *Ex. 4, pp. 27-33.* With its request for authorization, the Supplier presents a statement from Dr. Ali Choucair, MD who identifies himself as the Beneficiary's physician. Dr. Choucair requests authorization to "initiate treatment with the Device at Norton Hospital – Kentuckiana Cancer Institute," which is indicated to be a facility which played a role in clinical trials for the device "and was one of the first hospitals in the nation to obtain manufacturer certification to use the

¹ The Device is coded E0766. The Medicare Pricing, Data Analysis and Coding Contractor, Noridian Healthcare Solutions website confirms that this code does not appear on the CMS National Fee Schedules available in DMECS, and that "If you would like instructions on how to bill this product, contact your DME MAC for pricing assistance." www.dmeptac.com, (11/6/14)

device commercially following its FDA approval." *Ex. 4, p. 28*. Dr. Choucair indicates that the Device is a prescription only, non-invasive device that is intended for continuous use throughout the day by the patient. *Ex. 4, p. 29*.

The file does not reflect the original Plan denial, but does include the request for redetermination filed by the Supplier as the appointed representative of the Beneficiary. Therein, the Supplier argues that the Device is FDA approved for the Beneficiary's condition, glioblastoma multiforme (GBM), attaching among other things medical records and a letter of medical necessity from "Lansea Coombe, PA to Dr. Renato Larocca, MD" of Norton Hospital – Norton Cancer Institute. *Ex. 4, pp. 22-26*.

On redetermination, the Plan again denied coverage, stating that the diagnosis was glioblastoma for which authorization of electrical stimulation device used for cancer treatment, including supplies, has been requested. The Plan acknowledged that the medical record indicates the member has failed other treatments for brain cancer. However, the Plan again denied payment because Local Coverage Determination L34730 for New Hampshire, titled "Tumor Treatment Field Therapy (TTFT)" indicates that "Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary." *Ex. 4, pp. 13-14.A*

As required pursuant to Medicare rules, the Plan forwarded the denial to the Independent Review Entity, (also called the Part C QIC) Maximus Federal Services, who again denied the claim on the grounds that LCD L34730 provides that treatment with the device is not reasonable and necessary.

On or about September 14, 2014, the Part C QIC received a request for Administrative Law Judge ("ALJ") hearing filed by the Supplier as the Beneficiary's representative, which was forwarded to the Office of Medicare Hearings and Appeals on September 24, 2014. The request was timely and the amount in controversy satisfies the jurisdictional requirement for an ALJ hearing pursuant to Title XVIII of the Social Security Act (the "Act" or "Title XVIII") Sections 1852(g)(5) and 1869(b)(1)(E).

A telephonic hearing was held on November 3, 2014. The Beneficiary and his wife Patricia Howard were present and testified. In addition, the Supplier's representatives, Justin Kelly, Sr. Director of Health Policy and Payment, and Dan McCoy, Case Manager, appeared and/or testified on behalf of the Beneficiary. Dr. Renato Larocca, MD, the Beneficiary's current treating oncologist, also appeared and testified on behalf of the Beneficiary. The Plan was represented Dr. Kathleen O'Connell, MD, Medical Director and Katrina Jewell, Medicare Grievance & Appeals Specialist. Exhibits 1 – 12 have been admitted into evidence. Good cause is found for the admission of new documentation submitted to the ALJ, due to the need for updated documentation concerning the Device efficacy, and ongoing treatment of the Beneficiary and need for review of updated medical records to determine the current medical need of the Beneficiary for the Device related to this request for prior authorization. *See 42 C.F.R. §§405.1018, 1028* (requiring a finding of good cause to admit evidence first submitted at ALJ level of appeal).

III. ISSUES

The issue is whether the Plan must authorize coverage for the treatment with the NovoTTF-100APlus Transducer Device, coded by HCPCS Code E0766, i.e. is the Device covered and payable by the Plan pursuant to Section 1851 et seq. of Title XVIII (Medicare Part C).

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IV. LEGAL FRAMEWORK

The Medicare program, Title XVIII of the Social Security Act (42 U.S.C. §§ 1395 – 1395ccc), is administered through the Centers for Medicare and Medicaid Services, or CMS. Title 42 of the Code of Federal Regulations, (“C.F.R.”), Chapter IV contains implementing regulations. Centers for Medicare and Medicaid Services, (“CMS”) Rulings and Manual Guidance and National and Local Coverage Determinations may also be cited herein, when applicable.²

I. ALJ Review Authority

Plan determinations are subject to appeals procedures set forth under the Medicare Advantage Program, also known as Medicare Part C.

A. Jurisdiction

An enrollee who receives an adverse Medicare Advantage (“MA”) plan determination, including the MA organization’s refusal to provide or pay for services in whole or part, is entitled to a Reconsideration by the MA organization, and if not thereafter satisfied, to a subsequent Reconsideration to be performed by an Independent Review Entity, or, IRE. *See Section 1852(g) of Title XVIII; 42 C.F.R. §§422.566; 422.576-596.*

Enrollees or providers dissatisfied with the IRE’s Reconsideration are entitled to a hearing before the Secretary of the Department of Health and Human Services (“HHS”), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. *See Section 1852(g)(5) of Title XVIII; 42 C.F.R. §§422.600-602.*

In implementing this statutory directive, the Secretary has delegated her authority to administer the nationwide hearings and appeals system for the Medicare program to the Office of Medicare Hearings and Appeals (“OMHA”). *See 70 Fed. Reg. 36386-36387 (June 23, 2005); See also 42 C.F.R. §§422.600-602.*

The Administrative Law Judges, ALJs, within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *Id.; See also 42 C.F.R. §422.608.* The parties to the ALJ hearing may include the plan enrollee (also referred to herein as the beneficiary or member), an assignee of the enrollee (that is, a physician or other provider who has furnished a service to the enrollee and formally agrees to waive any right to payment from the enrollee for that service), the legal representative of a deceased enrollee’s estate, the MA organization (i.e. the Plan), and any other person, provider or entity whose rights may be affected by the hearing as determined by the ALJ or at any lower level of appeal. *See 42 C.F.R. §422.602(c); See also 422.574; 422.582(d); 422.592(c).*

The request for an ALJ hearing is timely if filed within sixty days after receipt of a Reconsideration issued by the IRE. *See 42 C.F.R. §422.602.* To be entitled to an ALJ hearing, a party must meet the minimum amount in controversy requirement of \$100; however, this minimum is subject to increases which are published in the Federal Register. *42 C.F.R. §§405.1006; 422.600.* The amount in controversy threshold for ALJ hearing requests filed during 2014 is \$140. *78 Fed. Reg. 59702-59704 (September 27, 2013).*

² Many of the sources cited herein are available at www.cms.gov.

B. Scope of Review

In hearing appeals under Medicare Part C, the ALJ generally applies the same administrative review and hearing processes that are employed in reviewing cases under Original Medicare Parts A and B. 42 C.F.R. §422.562(d). Thereunder, the ALJs conduct *de novo* hearings.³ See 70 Fed. Reg. 36386, 36387 (June 23, 2005); 42 C.F.R. §405.1000(d). The issues before the ALJ include all the issues brought out in the Plan determination, Plan reconsideration or IRE reconsideration that were not decided entirely in the appellant's favor. However, if evidence presented before the hearing causes the ALJ to question a favorable portion of the determination, notice will be sent to the appellant and it will be considered at the hearing. See 42 CFR 405.1032.

All laws, regulations and Centers for Medicare and Medicaid Services ("CMS") rulings pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Social Security Act and applicable implementing regulations are binding on ALJs. 42 C.F.R. §405.1063.

The Administrative Law Judge's, or ALJ's, application of National Coverage Determinations ("NCDs"),⁴ written coverage decisions of Medicare contractors, also called Local Coverage Determinations, or LCDs⁵, and CMS manual guidance is also addressed under Medicare law. Section 1871(a)(2) of Title XVIII provides that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than an NCD, can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. Medicare Regulations at 42 C.F.R. 405.1060, 4) provide that an applicable NCD is binding on ALJs. Medicare Regulations at 42 CFR §405.1062 provide that in making coverage determinations ALJs will give substantial deference to policy guidance including applicable LCDs or CMS program guidance, such as program memoranda and manual instruction. However, an ALJ is not required to follow such policy guidance. An explanation in the decision is required if the ALJ does not follow such policy guidance.

II. Medicare Part C – Medicare Advantage Plan Coverage

A. General Framework for Medicare Part C

Section 1851 et seq. of Title XVIII establishes the Medicare Advantage Program, also referred to as Medicare Part C, which permits eligible individuals to receive Medicare benefits through enrollment in a private health insurance plan, typically referred to as a Medicare Advantage, or MA plan.

Medicare Regulations at 42 C.F.R. Part 422 provide rules governing the Medicare Advantage Program.

³ In a *de novo* review, the ALJ conducts a new and independent review of the record and is not bound by any previous decision(s) issued in a case.

⁴ An NCD is a determination by the Secretary of whether a particular item or service is covered nationally. See 42 C.F.R. §405.1060.

⁵ An LCD is an Original Medicare Part A or B contractor-wide written policy coverage determination as to whether particular items or services are medically reasonable and necessary. See 42 C.F.R. §400.202.

Medicare Managed Care Manual, Pub. 100-16, ("CMS Pub. 100-16") also offers guidance regarding the Medicare Advantage Program.

This authority explains that the benefits offered by an MA plan are reviewed and approved by CMS to ensure that Medicare guidelines have been met. 42 C.F.R. §§422.100(f); CMS Pub. 100-16, Ch. 4, §10.2.1. The plan provides eligible enrollees, at a minimum, basic benefits, which include all medically necessary Medicare covered Part A and Part B services, except hospice services, certain clinical trial services and certain service during inpatient stays during which MA plan enrollment begins or ends. MA plans may also include mandatory and/or optional supplementary benefits. See *Id.*; 42 C.F.R. §§422.100(a), (e); 422.101(a).⁶

With respect to the required Original Medicare benefits, a Medicare Advantage Organization, or MAO (i.e. the plan)

An MA organization (MAO) offering an MA plan must provide enrollees in that plan with all Part A and Part B, Original Medicare services, if the enrollee is entitled to benefits under both parts, and Part B services if the enrollee is a grandfathered "Part B only" enrollee. The MAO fulfills its obligation of providing Original Medicare benefits by furnishing the benefits directly, through arrangements, or by paying on behalf of enrollees for the benefits.

Administration of the Medicare program is governed by Title XVIII of the Social Security Act (the Act). Under the Medicare program, the scope of benefits available to eligible beneficiaries is prescribed by law and divided into several main parts. Part A is the hospital insurance program and Part B is the voluntary supplementary medical insurance program.

The scope of the benefits under Part A and Part B is defined in the Act. The scopes of Part A and Part B are discussed in sections 1812 and 1832 of the Act, respectively, while section 1861 of the Act lays out the definition of medical and other health services. Specific health care services must fit into one of these benefit categories, and not be otherwise excluded from coverage under the Medicare program (see §1862 for exclusions).

In general, the Act lists categories of items and services covered by Medicare, although Congress occasionally adds specific services to be covered by Medicare. Some categories are defined more broadly than others; for example, the Act includes hospital outpatient services furnished incident to physicians' services (§1861(s)(2)(B)) but also specifically includes diabetes screening tests (§1861(s)(2)(Y)). The Act vests in the Secretary the authority to make determinations about which specific items and services, within categories, may be covered under the Medicare program. Further interpretation is provided in the Code of Federal Regulations and CMS guidance.

Medicare coverage and payment is contingent upon a determination that:

- A service is in a covered benefit category;

⁶ Medicare Part D prescription drug benefits may also be offered through MA organizations in conjunction with their MA plan. See 42 C.F.R. §§422.4(c).

- * A service is not specifically excluded from Medicare coverage by the Act; and
- * The item or service is "reasonable and necessary" for the diagnosis or treatment of an illness or injury or to improve functioning of a malformed body member, or is a covered preventive service.

CMS Pub. 100-16, Ch. 4, §10.2.

In addition to providing Original Medicare benefits, to the extent applicable, the Medicare advantage organization, or MAO, also furnishes, arranges, or pays for supplemental benefits and prescription drug benefits to the extent they are covered under the plan. *CMS Pub. 100-16, Ch. 4, §10.2.1.*

There are three basic types of MA plans open to all MA-eligible Medicare beneficiaries residing in the authorized service area of the plan include: (1) Coordinated Care Plans, or CCPs, (2) Private Fee-For Services, or PFFS, plans, and (3) Medical Savings Account, or MSA, plans. *See 42 C.F.R. §422.4; CMS Pub. 100-16, Ch. 1, §§30.1-30.2.2.* A CCP is a plan that includes a network of providers that are under contract or arrangement with the organization to deliver the benefit package approved by CMS. The CCP network is approved by CMS to ensure that all applicable requirements are met, including access and availability, service area, and quality requirements. A PPO such as provides coverage for the Beneficiary in this case has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; and, provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; only for purposes of quality assurance requirements in §422.152(e), is offered by an organization that is not licensed or organized under State law as an HMO; and, does not permit prior notification for out-of-network services — that is, a reduction in the plan's standard cost-sharing levels when the out-of-network provider from whom an enrollee is receiving plan-covered services voluntarily notifies the plan prior to furnishing those services, or the enrollee voluntarily notifies the PPO plan prior to receiving plan-covered services from an out-of-network provider. *See Id.; CMS Pub. 100-16, Ch. 1, §§30.2.3.*

Medicare Regulations at 42 C.F.R. §422.11 state that an MA plan must disclose the benefits offered under a plan, including applicable conditions and limitations, premiums and cost-sharing (such as copayments, deductibles, and coinsurance) and any other conditions associated with receipt or use of benefits to its enrollees. This information may be found in the MA Plan Evidence of Coverage, ("EOC"), which MA plans provide to enrollees upon enrollment, on an annual basis and through the plan's internet web site. These disclosure rules are also discussed in CMS Pub. 100-16, Ch. 3. All such marketing materials used by plan sponsors or their subcontractors must be submitted by the plan sponsor (or its designee) to CMS for review and approval (or acceptance). *See CMS Pub. 100-16, Ch. 3, §30.5.*

In making benefit determinations, the MA organization complies with CMS's national coverage determinations (NCDs), general coverage guidelines included in CMS's Medicare manuals and instructions (unless modified by Federal regulations or related instructions), and applicable written coverage decisions of Original Medicare contractors (e.g. LCEs) with jurisdiction for claims in the geographic area in which such services are covered under the MA plan. (If an MA plan covers

geographic areas encompassing more than one local coverage policy area, the MA organization offering such an MA plan may elect to apply to plan enrollees in all areas uniformly the coverage policy that is the most beneficial to MA enrollees.) *See 42 C.F.R. §422.101(b).*

B. Plan Evidence of Coverage (EOC)

Because the Plan discloses its covered benefits in its Evidence of Coverage, or EOC, it is necessary to review that document to determine policy coverage. In pertinent part, your Plan EOC states that services that are covered for you include "[d]urable medical equipment (DME) and related supplies." Prior authorization is required requested when you get the item out of network, and required when you get the items in network or "for any DME item over \$750." *EOC, pp. 63-64, Chapter 4, Section 2.1, Medical Benefits Chart.* A 4% coinsurance is required when you get the services at a durable medical equipment provider, whether in or out of network. *Id.*

Your EOC further explains that

- "Your Medicare covered services must be provided according to the coverage guidelines established by Medicare." *EOC, p. 53, Chapter 4, Section 2.1.*
- "Except in the case of preventative services and screening tests, your services (including medical care, services, supplies, and equipment) *must* be medically necessary. 'Medically necessary' means that the services, supplies, or drugs are needed for the prevention, diagnosis, or treatment of your medical condition and meet accepted standards of medical practice." *Id.*

C. Pertinent Original Medicare Coverage Rules

Because Medicare rules provide that your Medicare Part C Medicare advantage plan must include benefits provided under and according to Medicare coverage guidelines established by Original Medicare Parts A and B, it is also instructive to review those guidelines, as established by statute, regulation, NCD, LCD and CMS manual guidance.

Sections 1831 et seq. of Title XVIII establish the Supplementary Medical Insurance Benefits for the Aged and Disabled (Medicare Part B). Section 1832 of Title XVIII and Medicare Regulations at 42 C.F.R. §410.3 establish the scope of benefits that are provided to eligible beneficiaries under the Medicare Part B insurance program, which includes "medical and other health services." Sections 1832(a)(1), 1861(n),(s)(6) and 1834(a)(13) of Title XVIII and Medicare Regulations at 42 C.F.R. §410.38(a) provide that covered "medical and other health services" under Medicare Part B include, among many other things, the rental or purchase of durable medical equipment ("DME"), if the equipment is used in the patient's home or in an institution that is used as a home.

Section 1862(a)(1)(A) of Title XVIII provides that "[n]otwithstanding any other provision of the Act, no payment shall be made for any expenses incurred for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." *See also 42 CFR §411.15(k).*

The Manuals issued by the Centers for Medicare & Medicare Services ("CMS") serve to clarify and explain the various coverage requirements stated in the statute and regulations.

Medicare National Coverage Determinations Manual, Pub. 100-03 ("CMS Pub. 100-03"), Ch. 1, includes National Coverage Determinations. CMS Pub. 100-03, Ch. 1, §280.1 explains that the term Durable Medical Equipment, or DME, is defined as equipment which:

- Can withstand repeated use; i.e., could normally be rented, and used by successive patients;
- Is primarily and customarily used to serve a medical purpose;
- Generally is not useful to a person in the absence of illness or injury; and
- Is appropriate for use in a patient's home.

Medicare Benefit Policy Manual, Pub. 100-02 ("CMS Pub. 100-02"), Ch. 15, §110, also provides guidance pertaining to Medicare coverage of DME, and explains that:

Expenses incurred by a beneficiary for the rental or purchases of durable medical equipment (DME) are reimbursable if the following three requirements are met:

- The equipment meets the definition of DME [see above];
- The equipment is necessary and reasonable for the treatment of the patient's illness or injury or to improve the functioning of his or her malformed body member (§110.1); and
- The equipment is used in the patient's home.

CMS Pub. 100-02, Ch. 15, §110(c) provides guidance as to the "necessary and reasonable" requirement, and states as follows:

Although an item may be classified as DME, it may not be covered in every instance. Coverage in a particular case is subject to the requirement that the equipment be necessary and reasonable for treatment of an illness or injury, or to improve the functioning of a malformed body member. These considerations will bar payment for equipment which cannot reasonably be expected to perform a therapeutic function in an individual case or will permit only partial therapeutic function in an individual case or will permit only partial payment when the type of equipment furnished substantially exceeds that required for the treatment of the illness or injury involved.

1. Necessity for the Equipment

Equipment is necessary when it can be expected to make a meaningful contribution to the treatment of the patient's illness or injury or to the improvement of his or her malformed body member. In most cases the physician's prescription for the equipment and other medical information available to the DMERC will be sufficient to establish that the equipment serves this purpose.

2. Reasonableness of the Equipment

Even though an item of DME may serve a useful medical purpose, the DMERC or intermediary must also consider to what extent, if any, it would be reasonable for the Medicare program to pay for the item prescribed. The following considerations should enter into the determination of reasonableness:

1. Would the expense of the item to the program be clearly disproportionate to the therapeutic benefits which could ordinarily be derived from use of the equipment?

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2. Is the item substantially more costly than a medically appropriate and realistically feasible alternative pattern of care?
3. Does the item serve essentially the same purpose as equipment already available to the beneficiary?

3. Payment Consistent With What is Necessary and Reasonable

Where a claim is filed for equipment containing features of an aesthetic nature or features of a medical nature which are not required by the patient's condition or where there exists a reasonably feasible and medically appropriate alternative pattern of care which is less costly than the equipment furnished, the amount payable is based on the rate for the equipment or alternative treatment which meets the patient's medical needs.

The acceptance of an assignment binds the supplier-assignee to accept the payment for the medically required equipment or service as the full charge and the supplier-assignee cannot charge the beneficiary the differential attributable to the equipment actually furnished.

4. Establishing the Period of Medical Necessity

Generally, the period of time an item of durable medical equipment will be considered to be medically necessary is based on the physician's estimate of the time that his or her patient will need the equipment. See the Medicare Program Integrity Manual, Chapters 5 and 6, for medical review guidelines.

Local Coverage Determination L34730, titled "Tumor Treatment Field Therapy (TTFT)" issued by Medicare DME Contractor NHIC Corp., ("LCD L34730") states "Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary." The pertinent Local Coverage Determinations, or LCDs, and related Policy Article A52680, also issued by Medicare DME Contractor NHIC Corp., are further addressed below under Findings of Fact.

Medicare Program Integrity Manual, Pub. 100-08 ("CMS Pub. 100-08"), Ch. 5, also provides guidance as to documentation requirements to support that Medicare coverage criteria for items of DME have been met. Chapter 5, Section 5.7 states as follows, in pertinent part:

For any DMEPOS item to be covered by Medicare, the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the patient's diagnosis and other pertinent information including, but not limited to, duration of the patient's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc. . . . neither a physician's order nor . . . a supplier prepared statement nor a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier. There must be information in the patient's medical record that supports the medical necessity for the item and substantiates the answers on the CMN [certificate of medical necessity] (if applicable) or DIF [DME information form] (if applicable) or information on a supplier prepared statement or physician attestation (if applicable).

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V. FINDINGS OF FACT

The medical record

The record as received from the Independent Review Entity, Maximus, includes a prescription and order for the Device signed by Dr. Ali Choucair, who is a board certified neuro-oncologist (as confirmed by the testimony of Dr. Larocca), for use by the Beneficiary for six months for treatment for the Beneficiary's diagnosis of Glioblastoma Multiforme, identified by ICD-9 code 191.9 (Malignant neoplasm of brain, unspecified), with a requested start date of September 3, 2014. *Ex. 3, p. 1.* (The record indicates that treatment has not, in fact, commenced pending the outcome of this appeal.) This medical record includes an August 13, 2014 progress note from Dr. Choucair, indicating that the Beneficiary "is [here] for a follow up brain MRI." *Ex. 3, p. 2.* The progress note states that the Beneficiary has a diagnosis of GBM, and states "Oncology Treatment Summary: Previous Therapy, Craniotomy x2, Radiation x2, Avastin." *Id.* The progress note further identifies that concurrent radiation treatment plus chemotherapy with Temodor was completed on June 15, 2012, with Temodor induced thrombocytopenia during radiation treatment documented. Specifically, a post-radiation treatment challenge with low dose of Temodor resulted in thrombocytopenia and discontinuation of Temodor. *Id.* In the August 13, 2014 progress note, Dr. Choucair indicates that a neurological examination revealed the Beneficiary to be much more fatigued, with left optic neuropathy with light and color desaturation out of proportion to the Beneficiary's cataract. Dr. Choucair identifies a Diagnosis/Assessment/Plan including "1. GBM: multiple surgeries, Radiation course x2, Avastin (chemotherapy-induced bone marrow failure). He is unfortunately slowly failing. He is not a candidate for further surgery or Chemotherapy. I reviewed with them the Novo-TFF: he would like to be considered for it." *Ex. 3, p. 4.*

In the progress note, Dr. Choucair further indicates "I brought up today's [August 13, 2014 MRI] films and reviewed with them: there is progression the T2 flair without change in contrast enhancement. This is the pattern commonly seen with early Avastin failure." *Ex. 3, p. 4.* The August 13, 2014 MRI report itself indicates no recurrent GBM was shown, but does confirm the T2 anomaly addressed by Dr. Choucair as follows:

- "1. No evidence of new or progressive nodular enhancement to suggest recurrent glioblastoma.
2. There is progressive T2 prolongation within the left cerebrum in a both diffuse as well as focal pattern. The diffuse progression is seen within the corona radiata and centrum semiovale and this represents a slight gradual progression over the series of recent postoperative MRIs dating to 2013. This has the appearance of likely treatment-induced vasculopathy.
3. There are progressive more focal regions of increased T2 signal seen within the anterior aspect of the left lentiform nuclei and internal capsule. Based on absence of mass effect and appearance of progressive treatment related vasculopathy rather than recurrent disease. Continued standard MRI imaging follow-up is recommended.
4. Improving postoperative subdural hematoma which now has the appearance of chronic postoperative meningeal thickening. No new hemorrhage or progressive hemorrhage is identified."

Ex. 3, pp. 5-7.

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A more recent October 13, 2014 MRI report has now been submitted, which indicates an impression of a "new 1.3-cm enhancing nodule in the left temporal stem; new 1.0-cm T2 hyperintense lesion in the left subinsular white matter. These lesions are concerning for disease progression." *Ex. 8.* With the new MRI report, an October 13, 2014 progress note from the Beneficiary's new neuro-oncologist, Dr. Larocca (who also testified at the hearing) has been submitted on behalf of the Beneficiary. (At the hearing, Ms. Howard confirmed that Dr. Larocca has taken over the Beneficiary's care from Dr. Choucair, who is no longer available to the Beneficiary - Dr. Choucair "left"). Dr. Larocca's progress note describes the results of the October 13, 2014 MRI and also includes a review of the Beneficiary's medical history, generally consistent with the above earlier presented documentation, but with additional details and an updated medical status of the Beneficiary. *Ex. 9.*

In his October 13, 2014 progress note, as confirmed by his testimony at the hearing, Dr. Larocca explains that the Beneficiary is a 67 year old diagnosed on April 2012 with a left temporal gliosarcoma/glioblastoma multiforme. The Beneficiary underwent surgery at that time, and subsequently received radiation together with Temozolomide, also called Temodor, (which the hearing testimony confirms is chemotherapy) treatment with a completion date of June 2012, complicated by thrombocytopenia resulting in discontinuation of Temozolomide. The Beneficiary subsequently remained stable until May of 2013, at which time there was MRI evidence of recurrence of the initial tumor. On July 26, 2013, the Beneficiary underwent neurosurgical re/resection. The concurrent pathology report histologically confirmed glioblastoma in the specimen removed from the Beneficiary's left temporal lobe, which Dr. Larocca confirmed at the hearing would be considered a recurrence in the supratentorial region of the brain after receiving chemotherapy.⁷ The Beneficiary then suffered a subdural hematoma following a fall, and received additional palliative radiation therapy from November 18 through December 4, 2013 together with Avastin. Dr. Larocca further confirmed that Avastin is not considered a chemotherapy treatment, but is FDA approved for patients with GBM. Dr. Larocca also confirmed that although Avastin does not induce bone marrow suppression typical of chemotherapy treatments, it does have other side effect including fatigue. An MRI from March of 2014 then showed that the Beneficiary was stable. A following MRI from August 13, 2014 (identified above) was described by Dr. Larocca, in his progress note as demonstrating no new or progressive nodular enhancement, though the Beneficiary was experiencing progressive fatigue and a decision was made to discontinue Avastin. *Ex. 9.* At the hearing, Dr. Larocca further explained that the T2 flair shown in the August 13, 2014 MRI could be considered evidence of early progression of the disease, though not blatant evidence of such.

In his October 13, 2014 progress note, Dr. Larocca also describes the results of the October 13, 2014 MRI as indicating progression of the disease (glioblastoma multiforme), with a plan to reinstitute Avastin and continue attempts to obtain the Device at issue in this hearing. *Ex. 9.* I find that this medical record serves to confirm the hearing testimony of Dr. Larocca that surgical (x2)

⁷ Subsequent to the hearing, additional progress notes were submitted generally supportive of Dr. Larocca's testimony and medical history included in his October 13, 2014 progress note, including: a July 26, 2013 operative report pertaining to a left temporal craniotomy for resection of tumor and associated pathology report confirming glioblastoma in the specimen removed from the left temporal mass. *Ex. 11.*

and radiation (also x2) options have been exhausted for treatment of the Beneficiary's GBM. Dr. Larocca further expressed his concurrence at the hearing with the earlier decision of Dr. Choucair to try to proceed with the Device given the Beneficiary's medical history in this case.

TTF Treatment and Literature

Pursuant to an informal benefit category determination (BCD) issued by the CMS Director of DMEPOS Policy on July 26, 2013, the NovoTTF-100A System is a non-invasive system used in the patient's home that delivers tumor treating fields therapy to the brain to disrupt rapid cell division exhibited by recurrent GBM tumors, comprised of a durable electrical field generator and disposable insulated transducer arrays for use with the generator which meets the Medicare definition of durable medical equipment (DME) in that it: can withstand repeated use; has an expected life of at least three years; is primarily and customarily used to serve a medical purpose; generally is not useful to a person in the absence of an illness or injury; and is appropriate for use in the home. *Ex. 12, p. 12. See also Policy Article A52680* (indicating that tumor field therapy devices are covered under the Medicare DME benefit, so long as other requirements such as reasonable and necessary requirements are met).

The submitted Novocure "NOVOTTF-100A System Product Dossier," found at Exhibit 2 in the file, identifies that this product is an FDA Approved Treatment for Recurrent Glioblastoma Multiforme, and includes technical information and studies related to this FDA approval. The Dossier' bibliography cites articles and studies as sources, with dates from 1995 through 2012. *Ex. 2, pp. 46-48.* The bibliography also refers to the 2011 FDA approved Instructions for Use and the Summary of Safety and Effectiveness Data for the NovoTTF-100A System. Appendix A to the Dossier identifies an FDA April 8, 2011 Premarket Approval letter, which states as follows:

Indication for Use: The NovoTTF-100A is intended as a treatment for adult patients [22 years of age or older] with histologically-confirmed glioblastoma multiform (GBM), following histologically – or radiologically-confirmed recurrence in the supra-tentorial region of the brain after receiving chemotherapy. The device is intended to be used as monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted.

Ex. 2, p. 23.

This approval language is confirmed by the undersigned ALJ as included in the FDA's April 8, 2011 premarket approval letter, as available on at www.fda.gov.⁸ The testimony of the Supplier's representative, Mr. Kelly, confirms that the post-approval study required by the premarket approval letter is currently underway with patients at multiple sites throughout the United States. Mr. Kelly further confirmed that the approval language remained in effect as of the date of the hearing, and had not been modified by the FDA.

⁸ An ALJ may obtain information that is publicly available, including information that is available to the general public via the Internet or in a printed publication such as, but not limited to, information available on a CMS or contractor Web site or information in an official CMS or DHHS publication (such as, but not limited to, provisions of NCDs or LCDs, procedure code or modifier descriptions, fee schedule data, and contractor operating manual instructions). *See 42 C.F.R. §405.1034.*

Mr. Kelly further confirmed at the hearing that in the Pivotal Trial relied upon by the Supplier to substantiate the safety and effectiveness of the Device, the median duration of treatment was 2.3 months, whereas in the Supplier's patient registry just published or to be published in the journal *Seminars on Oncology*, this was closer to 4 months. These patients wore the Device until the physician determined that it was inappropriate for them to do so. Mr. Kelly further confirmed that the Device was for home use of 18 hours per day, pursuant to the FDA approved labeling.

The submitted literature from the Supplier also includes copies of several articles and studies. Among this material, for example, is a 2012 overview by Gutin and Wong, (noted as funded by the Supplier, Novocure). This overview first reviewed studies of the Device as a monotherapy. In this respect, the Device was first applied to patients in a small feasibility trial in 2003, was involved in a pilot trial in 2004, and a further pivotal phase III, multicenter, randomized clinical study of 237 recruited patients from 2006 through 2009. The authors conclude that based on the results of the pivotal phase III study, the FDA approved the NovoTTF-100A, device on April 8, 2011, through the pre-market approval regulatory pathway. The authors note that the FDA concluded that the study results showed the Device to be comparable in efficacy to active chemotherapy, without many of the side effects associated with chemotherapies and with a better quality of life. The authors also review two studies of combined TTF therapy and chemotherapy, which were described by the authors as "promising." The authors concluded that TTF therapy has a superior safety profile with side effects that did not appear to overlap with other treatments, and that the rational combination of TTF therapy with specific pharmacologic agents may enhance tumor cell death because of potential additive or synergistic effects. The authors acknowledged that additional research could shed light on the optimal scheduling to achieve a synergistic effect on tumor growth leading to long-term tumor control and enhanced patient survival. *Ex. 2, pp. 65-71.*

At the hearing, Dr. Larocca also referenced a Stupp, Wong et al. study (a copy of which is included in the record) first published in the *European Journal of Cancer*,⁹ which concluded that NovoTTF-100A for Tumor Treatment Fields (TTF) therapy appeared to be comparable in efficacy and activity to chemotherapy regimens that are commonly used for recurrent glioblastoma, while toxicity and quality of life clearly favored TTF. *Ex. 2, pp. 42-59.*

Dr. Larocca further testified that after Avastin failure, or in the Beneficiary's case supreme intolerance of the drug, the probability of any chemotherapeutic agent having any benefit is probably in the range of 2-5%, and even then usually only for a very brief duration. Dr. Larocca further testified to relatively new data, that either has been or is about to be published in the journal *Seminars on Oncology*, that even looking at a patient population after progressing on Avastin who received the NovoTTS device, the duration of disease stability or progression free

⁹ Although the disputed device in this case does not fall into the category of a drug or chemotherapy agent, I note that the *European Journal of Cancer* is included in the Medicare list of acceptable peer-reviewed medical literature to be considered when determining a medically accepted indication for the off-label use of drugs or biologicals in an anti-cancer chemotherapeutic regimen. *Medicare Benefit Policy Manual, Pub. 100-02, Ch. 15, §50.4.5.*

interval is significantly longer than any other treatment reported in the literature, making it an appropriate treatment in the setting of the Beneficiary in this case, and, in Dr. Larocca's opinion the best treatment available for the Beneficiary, outside of experimental clinical trials for which Dr. Larocca indicates the Beneficiary was not eligible and/or are unproven. Dr. Larocca further testified, anecdotally, that he has used the Device on occasion for his patients, particularly in situations similar to the Beneficiary's situation in this case, and he has found the Device to be of benefit.

Local Coverage Determination L34730, issued by Medicare Contractor NHIC Corp. (responsible for payment of claims under original Medicare Part B), states that "Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary." The LCD cites a review of some 17 studies or articles as sources of information and basis for the LCD decision, with dates from 2007 through 2013, including some of the same studies cited in the Supplier's submitted literature. However, the LCD does not provide any specific analysis of the Contractor's review of these studies or any rationale for the determination that tumor treatment field therapy treatment is not reasonable and necessary for tumor treatment. There is some question as to why this particular LCD was chosen in this case.¹⁰ However, I note that the three other LCDs issued by different DME Medicare Contractors, also state that "Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary." See LCD L34665 issued by CGS Administrators; LCD L34734 issued by Noridian Healthcare Solutions; and, L34738 issued by National Government Services. Mr. Kelly testified that to his knowledge the LCD was written by the four regional DME Medical Directors and their staff, without consult with an advisory committee including neuro-oncologists or neuro-surgeons, resulting in his understanding that the LCDs are currently being reviewed by CMS at the request of the Supplier.

VI. ANALYSIS

I have reviewed the criteria necessary for Medicare coverage of the claimed Device, as such criteria have been established in accordance with the Plan EOC and the Medicare statutory, regulatory, and other guidance provisions pertinent to coverage under Part C of Title XVIII (Medicare Part C). Based thereupon, I have determined that the criteria for coverage have been met. Therefore, the Plan must authorize coverage for the claimed Device for use consistent with physician orders and the Device Supplier's product guidelines. See *NovoTTF-100A System Product Dossier, Description and Use of NovoTTF-100A System*, p. 20.

More specifically, Medicare coverage under the DME benefit requires that the item meet the definition of durable medical equipment, be reasonable and necessary for the treatment of the patient's illness or injury or to improve the functioning of his or her malformed body member as required by Section 1862(a)(1)(A) of Title XVIII (medical necessity), and be for home use. See

¹⁰ Medicare rules require an MA organization to comply with applicable written coverage decisions of Original Medicare contractors (e.g. LCDs) with jurisdiction for claims in the geographic area in which such services are covered under the MA plan. (If an MA plan covers geographic areas encompassing more than one local coverage policy area, the MA organization offering such an MA plan may elect to apply to plan enrollees in all areas uniformly the coverage policy that is the most beneficial to MA enrollees.) See 42 C.F.R. §422.101(h).

CMS Pub. 100-02, Ch. 15, §110 et seq. Sufficient documentation should be submitted to support the claim, including a physician's order and sufficient medical record documentation to support that Medicare criteria, including medical necessity, have been met. *See CMS Pub. 100-08, Ch. 5.*

In this case, there is no question that the claimed NovoTTF-100A System Device, coded pursuant to E0766 (electrical stimulation device used for cancer treatment, includes all accessories, any type) meets the Medicare definition of DME for home use. However, the Plan denied coverage based upon a Local Coverage Determination, which simply states, without explanation, that "Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary." Medicare Regulations at 42 CFR §405.1062 provide that in making coverage determinations ALJs will give substantial deference to policy guidance, including applicable LCDs. However, an ALJ is not required to follow such policy guidance upon providing an explanation in the decision as to why the guidance will not be followed. *See Id.*

In this case, although I have given substantial deference to the LCD, I decline to follow the LCD and instead find that the Device will be considered reasonable and necessary for this beneficiary for the FDA indicated condition as stated in the April 8, 2011 FDA pre-market approval letter issued for the Device.

In declining to follow the pertinent LCD for this beneficiary, I have considered the following criteria, as suggested by Medicare manual guidance: (1) whether the device can be expected to make a meaningful contribution to the treatment of the patient's illness or injury or to the improvement of his or her malformed body member; (2) whether the device can be considered a reasonable treatment, considering expense versus therapeutic benefits, comparative cost of feasible alternatives, and whether the device serves comparative purposes with other equipment or alternatives; (3) whether all features of the device are required for treatment of the Beneficiary's condition; and, (4) the period of time the DME will be considered medically necessary, which is generally based on the physician's estimate of the time that his or her patient will need the equipment. *CMS Pub. 100-02, Ch. 15, §110(c).*

Based upon consideration of the submitted peer reviewed literature and studies and medical testimony, I find that these conditions are met for use of the device for FDA indicated treatments in this beneficiary. I find that the Device as used consistent with FDA indications can be expected to make a meaningful contribution to the treatment of the Beneficiary's recurrent supratentorial glioblastoma multiforme, that the FDA requires that all feasible alternatives have been exhausted prior to use of the Device, that there are no features of the Device not required for treatment, and that the medically necessary duration of treatment can properly be determined by physician orders.

Therefore, I find that the Device will be considered reasonable and necessary for this beneficiary pursuant to the FDA indications for treatment stated in the April 8, 2011 FDA pre-market approval letter, as follows:

This device is indicated for treatment of adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme, following histologically – or radiologically – confirmed recurrence in the supratentorial region of the brain after

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receiving chemotherapy. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted.

April 8, 2011 FDA Premarket Approval Letter (found at www.fda.gov).

I also find that the request for pre-authorization of use of the Device in this beneficiary is in conformance with the foregoing FDA indications in this case. The medical record and testimony confirm that the Beneficiary suffers from recurrent histologically (July 2013 pathology report) and radiologically (August and October 2014 MRIs) confirmed supratentorial glioblastoma multiforme, following two surgical interventions, two radiation treatments and the use of chemotherapy treatment with Temodar (Temozolomide), as well as, in this case, additional treatment with Avastin. I find that this record further supports the testimony of Dr. Larocca that all such traditional options have been exhausted, and that accordingly FDA criteria are met for treatment with the Device.

Accordingly, the use of the Device pursuant to appropriate physician orders is found to be reasonable and necessary as required for Medicare coverage.

VII. CONCLUSIONS OF LAW

MA plans offered under Medicare Part C must generally provide or pay for medically necessary Original Medicare Part A and Part B covered items and services, though additional optional supplemental coverage may also be offered by an MA plan. *CMS Pub. 100-16, Ch. 4, §§10.2-10.3*. Benefits are disclosed to members through a variety of means, including a Plan Evidence of Coverage which is approved by the Centers for Medicaid & Medicare Services. *See 42 C.F.R. §422.11; CMS Pub. 100-16, Ch. 3*. The Appellant's request for pre-authorization of the NovoTTF-100APLus Transducer Device, HCPCS Code E0766, meets requirements for Medicare coverage because the device is shown to: meet the definition of DME, be reasonable and necessary for the treatment of the Beneficiary's recurrent glioblastoma multiforme, and be for use in the Beneficiary's home. *See Sections 1832(a)(1), 1834(a)(13), 1861(n),(s)(6), 1862(a)(1)(A) of Title XVIII 42 C.F.R. §410.38(a); CMS Pub. 100-02, Ch. 15, §1.10 et seq.* Accordingly, the Plan shall authorize coverage for treatment of the Beneficiary's recurrent glioblastoma multiforme with the Device pursuant to orders of an oncologist or other qualified physician trained in the use of the Device and consistent with Supplier guidelines.

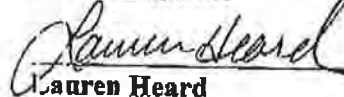
VIII. ORDER

The Plan is **DIRECTED** to process the claim in accordance with this decision.

Date

11/10/14

SO ORDERED.



Lauren Heard

U.S. Administrative Law Judge

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Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Irvine Field Office
Irvine, CA

Appeal of: **NOVACURE**

ALJ Appeal No.: **1-2813459974**

Beneficiary:

Medicare: **Part C**

HICN: *******4586A**

Before: **E. M. Koldewey**
U.S. Administrative Law Judge

DECISION

After careful consideration of the evidence and arguments presented in the administrative record and at the hearing, a **FULLY FAVORABLE** decision is entered in the matter of **Novacure (Appellant)** on behalf of Medicare Beneficiary **R. Quesenberry (Beneficiary/Enrollee)**.

PROCEDURAL HISTORY

The Medicare Beneficiary was enrolled in Humana Health Plan., a Medicare Advantage health plan ("Plan"), at the time of services at issue. (Exh. 1). He requested that his Plan pre-approve a tumor treatment field therapy (TTFT) device. On September 29, 2014, the Plan issued a denial for the approval on the grounds that per LCD L34665¹, TTFT (E0766) is denied as not reasonable and necessary. (Exh. 3, p. 42). Appellant appealed. On October 10, 2014, the Plan affirmed its denial and forwarded the appeal to an Independent Review Contractor, Maximus Federal Services Managed Care & PACE Reconsideration Project, for further review. (Exh. 3, p. 34). On October 14, 2014, Maximus² affirmed the Plan's unfavorable determination, finding that the Plan did not have pre-approve the tumor treatment field therapy (TTFT) device. (Exh. 3, p. 14).

The Appellant's request for a hearing before an Administrative Law Judge (ALJ) was received by the Office of Medicare Hearings and Appeals (OMHA) on December 5, 2014. (Exh. 3, p. 9). The appeal was timely filed and the amount in controversy met the jurisdictional requirements. *See* 42 C.F.R. § 405.1006; *see also* 75 Fed. Reg. 59138 (Sep. 23, 2011).

¹ In its September 2014 denial, the Plan referred to the TTFT LCD as LCD L34665 but in its October 2014 denial, the Plan referred to LCD 34730. Both LCDs refer to E0766 which is the service at issue.

² Maximus refers to the LCD for E0766 as LCD L34823; however, this LCD was not effective for the date of service at issue. For the purpose of this decision, the LCD that is being referenced is LCD L34730 which is applicable for Connecticut.

Pursuant to written notice, a telephonic administrative hearing was held on the Appellant's claim at OMHA in Irvine, California, on February 12, 2015. Hearing CD. D. McCoy, case manager, and M. Singleton, associate director, represented the Appellant. The Plan was represented by K. Jewell and Dr. C. McGuire-Dunn. Good cause was found for admission of Dr. Lesser's letter pursuant to 42 C.F.R. §§405.1018 & 405. All numbered exhibits (marked as Exhibits 1 through 10) were admitted into the evidentiary record without objection.

ISSUES

The hearing concerns the general issue of whether all Medicare coverage requirements are met for the services and/or supplies at issue, i.e., whether payment can be made under Title XVIII of the Social Security Act. The more specific issue is:

1. Is there sufficient evidence in the administrative record to establish that Humana Health Plan Inc. is required to pre-approve a tumor treatment field therapy (TTFT) device for R. Quesenberry pursuant to Medicare Part C and the Plan's Evidence of Coverage?

FINDINGS OF FACT

The following facts are established by a preponderance of the evidence:

The Medicare enrollee, a 44 year old male, was diagnosed with recurrent atypical grade II meningioma. In 1983, at age 13, he underwent a resection with shunt placement and radiation to treat three ependymomas. In 2002, he was diagnosed with right parasagittal meningioma WHO grade I and underwent a resection and gamma knife. He suffered a recurrence in 2008. In 2012, enrollee underwent a craniotomy and resection. In August 2013, he suffered from seizures and was noted to have several dural based masses consistent with recurrent meningioma and was started on Ilydrea. In January 2014, he began DIME infusional chemotherapy and CIVI-CAD chemotherapy. In September 2014, enrollee's physician, Glenn Lesser, MD, prescribed Novo TTF. Dr. Lesser determined that it was the best FDA approved option at this time for treating recurrent atypical grade II meningioma.

There is a letter of medical necessity submitted by Dr. Lesser dated September 17, 2014, requesting expedited review request for authorization of benefits coverage for a tumor treatment field therapy (TTFT). (Exh. 3, pp. 45-47).

In September 2014, Enrollee requested that his health plan, Humana, pre-approve a tumor treatment field therapy (TTFT) device. On September 29, 2014, the Plan issued a denial for the approval on the grounds that per LCD L34655 TTFT (E0766) is denied as not reasonable and necessary. (Exh. 3, p. 42). Appellant appealed. The Plan affirmed its denial and forwarded the appeal to an Independent Review Contractor, Maximus Federal Services Managed Care & PACE Reconsideration Project, for further review. (Exh. 3, p. 14). On October 14, 2014, Maximus affirmed the Plan's unfavorable determination, finding that the Plan did not have pre-approve a tumor treatment field therapy (TTFT) device finding that LCD 34823 states that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. *Id.*

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (“HHS”), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Sections 1852(g) and 1869(b)(1)(A) of the Act.

In implementing this statutory directive, the Secretary has delegated her authority to administer the nationwide hearings and appeals systems for the Medicare program to OMHA. *See* 70 Federal Register 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *Id.*

A hearing before an ALJ is available only if the remaining amount in controversy is \$140 or more. 42 C.F.R. § 405.1006; *see also* 75 Fed. Reg. 59138 (Sep. 23, 2011). The request for hearing is timely filed if filed within 60 calendar days after receipt of the QIC’s decision. 42 C.F.R. § 405.1002.

B. Scope of Review

Under the Centers for Medicare and Medicaid Services’ (“CMS”) implementation policy for the Medicare, Medicaid, SCHIP Benefits Improvement and Protection Act of 2000 (“BIPA”), Pub. Law 106-554, app. F, 114 Stat. 2763, 2763A-463, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”), Pub. Law 108-173, 117 Stat. 2066, when considering Medicare appeals, all initial determinations by CMS contractors, subsequent to January 1, 2006 and all appeals that were subject to a QIC reconsideration, are governed by the ALJ hearing procedures set forth at 42 C.F.R. §§ 405.1000 through 405.1064. *See* 70 Fed. Reg. 11420, 11424-26 (Mar. 8, 2005).

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the Appellant's favor. However, if evidence presented before or during the hearing causes the ALJ to question a favorable portion of the determination, he or she may notify the parties before the hearing and may consider it an issue at the hearing. 42 C.F.R. § 405.1032(a).

C. Standard of Review

An ALJ conducts a *de novo* review and issues a decision based on the hearing record. 42 C.F.R. § 405.1000(d). A *de novo* review means the ALJ reviews the evidence without regard to the findings in the prior determinations on the claim and makes an independent assessment based on the evidence and the controlling laws. However, the burden of proving each element of a Medicare claim lies with the Appellant and is satisfied by submitting sufficient evidence in accordance with Medicare rules. *See e.g.*, Sections 1814(a)(1), 1815(b), and 1833(e) of the Act; *see also* 42 C.F.R. § 424.5(a)(6), 42 C.F.R. §§ 405.1018, .1028, .1030.

An Appellant may offer new evidence for the first time at the ALJ level of appeal only upon a showing of good cause why the evidence was not submitted to the QIC or a prior decision maker. 42 C.F.R. § 405.1018. The ALJ will determine whether good cause exists for the late submission of the new evidence and may only consider the evidence in making a decision if good cause is found. *See also* 42 C.F.R. §§ 405.1028 and 405.1030. This late evidence restriction does not apply to unrepresented beneficiaries.

If the evidence in the hearing record supports a finding in favor of appellant(s) on every issue, the ALJ may issue a hearing decision without giving the parties prior notice and without holding a hearing. The notice of the decision informs the parties that they have the right to a hearing and a right to examine the evidence on which the decision is based. *See* 42 C.F.R. § 405.1038. The decision of the ALJ is generally binding on all parties to the hearing. *See* 42 C.F.R. § 405.1048.

II. Principles of Law

A. Statutes and Regulations

Title XVIII of the Act, as amended (42 U.S.C. §1395 *et seq.*), establishes a federally subsidized health insurance program (“Medicare”) to be administered by the Department of Health and Human Services. Eligibility for Medicare benefits is determined under Title XVIII of the Act and the federal regulations set forth in Title 42 of the Code of Federal Regulations (“C.F.R.”).

The Medicare Part C program establishes standards and sets forth the requirements, limitations, and procedures for Medicare services furnished, or paid for, by Medicare Advantage (“MA”) organizations through MA plans. *See* Act § 1851 *et seq.*; *see also* 42 C.F.R. § 422.1 *et seq.* A person is eligible to enroll in Part C if s/he is entitled to Medicare Part A and enrolled in Part B, has not been medically determined to have end-stage renal disease, and meets the applicable residency requirements. Act § 1851; 42 C.F.R. § 422.50(a).

An MA organization (“MAO”) offering an MA plan must provide enrollees in that plan with coverage for basic benefits (all Medicare covered services) by furnishing the benefits directly, through arrangements or by paying for such benefits, and CMS reviews the benefits. 42 C.F.R. §§ 422.100(a) and 422.101(a).

MAOs that offer coordinated care plans, such as the MA plan, may specify the network of providers from whom enrollees may obtain services, if the organization ensures that all covered services are available and accessible under the plan. Act § 1852(d); 42 C.F.R. § 422.112(a). To accomplish this, the MAO must maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served as well as provide or arrange for necessary specialty care. 42 C.F.R. § 422.112(a). An MAO must also arrange for specialty care outside of the plan provider network when network providers are unavailable or inadequate to meet an enrollee’s medical needs. *Id.* MA plan networks are approved by CMS to ensure that all applicable requirements are met, including access, availability, service areas and quality. 42 C.F.R. § 422.4.

B. Policy and Guidance

Section 1871(a)(2) of the Act provides that no rule, requirement or statement of policy, other than a national coverage determination (“NCD”), can establish or change a substantive legal standard governing the scope of the benefits or payment for services under the Medicare program unless promulgated as a regulation by CMS. *See also* 42 C.F.R. § 405.860. NCDs promulgated by the Secretary of HHS under the authority of § 1862(a)(1) of the Act dictate the criteria under which Medicare covers specified services, procedures or supplies. NCDs are binding upon ALJs. 42 C.F.R. § 405.732(a)(4). “An ALJ may not disregard, set aside or otherwise review an NCD.” 42 C.F.R. § 405.732(b)(1).

Although not subject to the force and effect of law, CMS and its contractors have issued policy guidelines, including manuals and local coverage determinations (“LCDs”), which describe coverage guidelines for selected types of medical items and services. The respective manuals issued by CMS provide guidance in the administration of the Medicare program. In *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87, 102 (1995), the United States Supreme court concluded that an agency manual section is a valid interpretive rule and that it is reasonable for the agency to follow it.

In providing “basic benefits,” an MAO must comply with NCDs, “[g]eneral coverage guidelines included in original Medicare manuals and instructions unless superseded by operational policy letters or regulations . . . ,” and LCDs issued by Medicare contractors with jurisdiction for claims in the geographic area.³ 42 C.F.R. § 422.101(b).

Pursuant to 42 C.F.R. § 405.1062(a), an ALJ is not bound by a manual or LCD, but will give substantial deference to it if it is applicable to a particular case. According to 42 C.F.R. § 405.1062(b), if an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed. An ALJ decision to disregard such a policy applies only to the specific claim being considered and does not have precedential effect.

The Medicare Policy Integrity Manual Chapter 13 states the following:

13.5.1 - Reasonable and Necessary Provisions in LCDs

(Rev. 473, Issued: 06-21-13, Effective: 01-15-13, Implementation: 01-15-13)

An item or service may be covered by a contractor LCD if:

- It is reasonable and necessary under 1862(a)(1)(A) of The Act. Only reasonable and necessary provisions are considered part of the LCD.

Reasonable and Necessary

Contractors shall describe in the draft LCD the circumstances under which the item or service is reasonable and necessary under 1862(a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and

³ MA plans covering more than one local coverage geographic area may adopt the local policy that is most beneficial to MA enrollees as a uniform policy for all plan enrollees. 42 C.F.R. § 422.101(b)(3).

- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
 - Furnished in a setting appropriate to the patient's medical needs and condition;
 - Ordered and furnished by qualified personnel;
 - One that meets, but does not exceed, the patient's medical need; and
 - At least as beneficial as an existing and available medically appropriate alternative.

There are several exceptions to the requirement that an item or service be reasonable and necessary for diagnosis or treatment of illness or injury. The exceptions appear in the full text of §1862(a)(1) and include but are not limited to:

- Pneumococcal, influenza and hepatitis B vaccines are covered if they are reasonable and necessary for the prevention of illness;
- Hospice care is covered if it is reasonable and necessary for the palliation or management of terminal illness;
- Screening mammography is covered if it is within frequency limits and meets quality standards;
- Screening pap smears and screening pelvic exam are covered if they are within frequency limits;
- Prostate cancer screening tests are covered if within frequency limits;
- Colorectal cancer screening tests are covered if within frequency limits; and
- One pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an interlobular lens;

LCD L34730, Tumor Treatment Field Therapy (TTFT) states the following relevant sections:

Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

For an item to be covered by Medicare, a detailed written order (DWO) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed DWO, the item will be denied as not reasonable and necessary.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

C. Evidence of Coverage

The Plan's EOC explains that the Plan covers items and services in accordance with Medicare rules. Exh. 1

ANALYSIS

The primary issue on appeal is whether Humana Health Plan Inc. is required to pre-approve a tumor treatment field therapy (TTFT) device for R. Quesenberry pursuant to Medicare Part C and the Plan's Evidence of Coverage. Based on a review of the evidence, the undersigned ALJ finds that the Plan is required to pre-approve a tumor treatment field therapy (TTFT) device for R. Quesenberry pursuant to Medicare Part C and the Plan's Evidence of Coverage.

Maximus determined that the Plan was not required to pre-approve the TTFT device finding that the requested service is not medically necessary under Medicare and the Humana plan and upheld the determination. Maximus determined that according to LCD L34730, TTFT (E0766) will be denied as not reasonable and necessary.

Pursuant to Medicare rules, a Medicare Advantage plan must provide its enrollees with coverage for all services covered by regular Medicare. *See* 42 CFR §422.101. The Plan's Evidence of Coverage also states that the Plan covers items and services in accordance with Medicare rules. In addition, LCD L34730, states that tumor treatment field therapy (TTFT)(E0766) will be denied as not reasonable and necessary.

In this case, the Medicare Enrollee, a [REDACTED], was diagnosed with recurrent atypical grade II meningioma. In 1983, at age 13, he underwent a resection with shunt placement and radiation to treat three ependymomas. In 2002, he was diagnosed with right parasagittal meningioma WHO grade I and underwent a resection and gamma knife. He suffered a recurrence in 2008. In 2012, Enrollee underwent a craniotomy and resection. In August 2013, he suffered from seizures and was noted to have several dural based masses consistent with recurrent meningioma and was started on Hydrea. In January 2014, he began DIME infusional chemotherapy and CIVI-CAD chemotherapy. Then in September 2014, Enrollee's physician, Glenn Lesser, MD, prescribed Novo TTFT. Dr. Lesser determined that it was the best FDA approved option at this time for treating recurrent atypical grade II meningioma.

At the hearing, Appellant's representatives corroborated Dr. Lesser's statement of medical necessity and noted that TTFT treatment was initiated for the Medicare Beneficiary on September 29, 2014, and that the Beneficiary continued to use the TTFT therapy until January 12, 2015. Appellant's representatives stated that TTFT is a non-invasive regional therapy that does not destroy other cells and helps slow cancer growth. The representatives also stated that the treatment is FDA-approved, safe, effective and exhibits minimum toxicity and resulted in better quality of life in control studies. Appellant's representatives cited many studies which showed the effectiveness of the therapy.

The Plan's representative, Dr. Dunn McGuire, stated that the health plan provides coverage according to Medicare rules. Dr. Dunn McGuire referred to the applicable LCD for E0766 which did not list any situation under which E0766 was reasonable and necessary. There were no provisions to qualify for coverage. Dr. Dunn McGuire testified that after review of the medical records from Dr. Lesser, the Plan maintained their original position which was to deny the pre-authorization for TTFT.

Based on the foregoing evidence in the medical record and at the hearing, the undersigned ALJ finds that there is sufficient evidence in the medical records to find TTFT (E0766) was medically reasonable and necessary in this case. While the applicable LCD states that E0766 will be denied as not reasonable and necessary, the undersigned ALJ declines to follow the LCD in this instant. Should an ALJ decline to follow a LCD, the decision must explain the reasons why the policy was not followed. *Id.* § 405.1062(b). In declining to follow the LCD, the undersigned ALJ examined the provisions in the Medicare Policy Integrity Manual regarding “reasonable and necessary.” The manual states that in making an individual determination as to whether an item or service is reasonable and necessary, contractors will analyze whether the item or service is safe and effective, and not experimental or investigational. In addition, contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational...; and
- Appropriate, including the duration and frequency that is considered appropriate for the service.

Using this as a reference, the undersigned ALJ finds that the medical records substantially document that TTFT therapy is safe and effective and not experimental or investigational in this case. As noted above, the treatment has been approved by the FDA. There are numerous clinical studies demonstrating the safety and effectiveness of the treatment. Moreover, as the medical records indicate and has been corroborated by Dr. Lesser, the TTFT treatment was appropriate for this Beneficiary given his extensive medical history, including resections, craniotomy, gamma knife treatments, recurrence and limited success with alternative treatments. It was reasonable for the physician to prescribe and initiate this treatment as it was the best FDA approved option at this time for treating recurrent atypical grade II meningioma for this Beneficiary. In addition, there is also no provision in the Plan’s Evidence of Coverage which specifically excludes TTFT treatment for recurrent atypical grade II meningioma.

Based on the foregoing evidence in the record and at the hearing, the undersigned ALJ finds that there is sufficient evidence to find that E0766 was appropriate for this Beneficiary. As the medical documents and studies show, E0766 is safe and effective, not experimental or investigational and has received FDA approval. The FDA approved the Novo TTF-100A system on April 15, 2011, for the treatment of adults with GBM that recurs or progresses after receiving chemotherapy and radiation therapy. There is sufficient documentation through controlled studies showing the effectiveness of the treatment. Although one of the studies is a Novacure funded study, other randomized studies concluded TTFT’s effectiveness. Therefore, the undersigned ALJ substantially defers to, but does not follow the applicable LCD and policy article which states that TTFT is not reasonable and necessary. Instead, the undersigned ALJ finds that TTFT was medically reasonable and necessary in this case as discussed above and finds that Humana Health Plan Inc. is required to pre-approve a tumor treatment field therapy (TTFT) device for pursuant to Medicare Part C and the Plan’s Evidence of Coverage.

CONCLUSIONS OF LAW AND ORDER

1. Humana Health Plan Inc. is required to pre-approve a tumor treatment field therapy (TTFT) device for . . . pursuant to Medicare Part C and the Plan's Evidence of Coverage.
2. The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated:

MAR 25 2020



E. M. Koldewey
U.S. Administrative Law Judge



OFFICE OF MEDICARE HEARINGS AND APPEALS

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December 22, 2015

ALJ Appeal Number: [REDACTED]

Appellant: [REDACTED] via Novocure

Novocure
Attn: Stacy Tarazewich
195 Commerce Way
Portsmouth, NH 03801

NOTICE OF DECISION

Enclosed is the Administrative Law Judge's decision for the above case. As explained below, the decision is binding unless it is appealed to the Medicare Appeals Council, or the Medicare Appeals Council reviews the case on its own motion.

This decision is based on the administrative record and any testimony presented to the Administrative Law Judge for the matter at issue. The decision is not *precedential*, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. Other parties may also appeal the decision. In addition, the Medicare Appeals Council may decide to review the decision on its own motion. If you or another party does not appeal the decision, and the Medicare Appeals Council does not review the decision, the decision is binding on all parties and you and the other parties will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree. You can do this by completing the enclosed *Request for Review* (Form DAB-101), or by writing a letter containing the following:

- The beneficiary's name;
- The beneficiary's health insurance claim number;
- The item(s) or service(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided;
- The date of the ALJ's decision; and
- Your name and signature, and, if applicable, the name and signature of your representative.

Mail your appeal and a copy of the enclosed decision to:

Department of Health and Human Services
 Departmental Appeals Board
 Medicare Appeals Council, MS 6127
 Cohen Building Room G-644
 330 Independence Ave., S.W.
 Washington, D.C. 20201

Or, you may fax your appeal to the Medicare Appeals Council at (202) 565-0227. If you send a fax, please **do not** also mail a copy.

You must always send a copy of your request for review to the other parties who received a copy of this decision.

How much time do I have to file an appeal?

The Medicare Appeals Council must receive your written appeal **within 60 days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

Additional information about filing an appeal with the Medicare Appeals Council is available at <http://www.hhs.gov/dab/>. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or 1-866-365-8204 (toll-free), if you have questions about filing an appeal.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to the Administrative Law Judge for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A contact phone number and mailing address are at the top of this notice.

Regards,

Barbara Klinghoffer

Barbara Klinghoffer
Legal Assistant to Judge Roger Davis

Bene: 

Copies were sent to the following parties and Medicare Contractors:

Humana
Attn: Shana Edwards
101 E. Main Street 10 SW
Louisville, KY 40202

Aurora Cancer Care
Attn: Dr. Dhimant Patel
2845 Greenbrier Road
P.O. Box 8900
Green Bay, WI 54308-8900

Maximus Federal Services
Appeals Work Station
Medicare Part C QIC
3750 Monroe Ave., Suite 702
Pittsford, NY 14534-1301

Enclosures:

OMHA-152, Decision
OMHA-156, Exhibit List



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, Missouri

Appeal of: [REDACTED]	ALJ Appeal No.: [REDACTED]
Beneficiary: [REDACTED]	Medicare Part C
HICN: *****0013A	Before: Roger Davis U.S. Administrative Law Judge

DECISION

This Judge decides this appeal **favorable** to [REDACTED] (the "Appellant") after holding a hearing.

Findings of Fact

The beneficiary and appellant, [REDACTED] is enrolled in a health plan (the Health Plan") that is offered by Humana, a Medicare Advantage Organization (MAO). [REDACTED] is seeking pre-approval from the Health Plan for coverage of Optune for treatment of his glioblastoma (current procedural terminology (CPT) code E0766). Optune is a relatively new approach to cancer treatment which uses tumor treating fields (TTFields) to interfere with the division of malignant cells. (Ex. 3, pp. 2-3.) TTFields therapy is a locally or regionally delivered treatment that uses alternating electric fields to disrupt the rapid cell division exhibited by cancer cells. (*Id.*) Patients treated with TTFields wear insulated transducer arrays on the scalp attached to the portable field generator. (*Id.*)

This device is manufactured by NovoCure, Ltd., and was approved by the Federal and Drug Administration (FDA) in April of 2011. (Ex. 3, pp. 110-14.)

[REDACTED] is a [REDACTED] year old gentleman who is diagnosed with glioblastoma. Glioblastomas (GBM) are tumors that arise from astrocytes—the star-shaped cells that make up the "glue-like," or supportive tissue of the brain. These tumors are usually highly malignant (cancerous) because the cells reproduce quickly and they are supported by a large network of blood vessels. See <http://www.abta.org/brain-tumor-information/types-of-tumors/glioblastoma.html>.

[REDACTED] presented with speech difficulty in July of 2015. (Ex. 3, pp. 2-3; Hearing CD.) An MRI revealed a mass in the left lateral temporal lobe. (*Id.*) On August 10, 2015, he underwent a

craniotomy¹ with pathology confirming GBM. (*Id.*) Dr. Dhimant Patel, [REDACTED]'s treating physician, testified that during the surgery he was able to remove most of the tumor. (*Id.*) Dr. Patel testified that following surgery, most patients relapse, and therefore they are started on radiation therapy with concurrent chemotherapy medication called Temozolomide. (*Id.*) [REDACTED] received five weeks of radiation therapy and is currently taking Temozolomide. (*Id.*)

Dr. Patel stated that recurrent glioblastoma multiforme is considered by the National Institutes of Health as an orphan disease due to its rarity and lack of approved treatment options. (Ex. 3, pg. 5; Hearing CD.) He stated that he has been treating brain tumors for thirty years and the treatment course described above of radiation therapy with Temozolomide has made an insignificant improvement in survival rates. (*Id.*) He testified that recent clinical studies of the effect of treating GBM patients with TTFields therapy with Temozolomide have shown significant improvements – approximately 50% – in survival rates. (*Id.*)

Dr. Patel also stated that [REDACTED] has failed systemic surgery, chemotherapy and all radiotherapy options approved for this clinical scenario. (*Id.*) Therefore, he certified that “there are few if any available options that would benefit the patient in this clinical scenario.” (*Id.*) He certified that “Optune is currently the only chronic treatment option for recurrent glioblastoma that has established its survival benefit and safety profile in a randomized controlled trial against a control arm receiving active effective therapy.” (*Id.*)

Mr. Dan McCoy, [REDACTED]'s representative who is affiliated with NovoCure, testified that the Health Plan has paid for this therapy for GBM patients in the past. (Hearing CD.) He also testified that there are approximately 230 treatment sites in the country with physicians who are certified to prescribe the therapy in question. (*Id.*)

Procedural History

[REDACTED] sought pre-approval from his health plan for coverage of Optune (TTFields therapy) for treatment of his glioblastoma. The Health Plan denied coverage for the treatment citing *NHIC Corp., Local Coverage Determination L34823: Tumor Treatment Field Therapy (LCD L34823) (Oct. 2015)*, which states that “Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.” (Ex. 1, pg. 13.) The Health Plan forwarded the appeal to MAXIMUS Federal Services, the Medicare Part C Qualified Independent Contractor (QIC), which also denied coverage of the treatment at issue citing to L34823. [REDACTED] then filed a request for a hearing before an Administrative Law Judge (ALJ) in the Office of Medicare Hearings and Appeals (OMHA).

This Judge conducted a hearing with the following participants on December 16, 2015: Dr. Dhimant Patel ([REDACTED]'s treating physician); [REDACTED] daughter); Mr. Dan McCoy ([REDACTED]'s representative, affiliated with NovoCure); and Ms. Cynthia McCloud (a representative of the Health Plan).

¹ A craniotomy is the surgical removal of part of the bone from the skull to expose the brain. Specialized tools are used to remove the section of bone called the bone flap. The bone flap is temporarily removed, then replaced after the brain surgery has been performed. See http://www.hopkinsmedicine.org/neurology_neurosurgery/centers_clinics/brain_tumor/treatment/surgery/craniotomy.html

Legal Framework

I. ALJ Review Authority

Health Plan enrollees who are dissatisfied with their Health Plan because they did not receive healthcare to which they believe they were entitled to, or because they contest the cost of a service they received, are entitled to an appeal process. Social Security Act § 1852(g), 42 U.S.C. § 1395w-22(g), 42 C.F.R. §§ 422.560, 422.562. The appeal process includes, if necessary, a hearing before an ALJ. 42 C.F.R. § 422.562(b)(4). An ALJ within the Office of Medicare Hearing and Appeals shall perform a *de novo* review of the case provided that there is a sufficient amount in controversy and that the appellant files the appeal in a timely fashion. 42 U.S.C. § 1395ff(b)(1)(A); *see also* 42 C.F.R. §§ 422.600, 405.1000 and 405.1002. *See generally* 70 Fed. Reg. 36386, 36387 (June 23, 2005) (delegation of Secretary's power specifically to OMHA to conduct reviews).

II. Principles of Law

Managed Care Organizations

A managed care organization (MAO) offering a Medicare Advantage (MA) plan must provide enrollees with “basic benefits,” which are all items and services covered by Medicare Part A and Part B available to beneficiaries residing in the plan’s service area. 42 C.F.R. § 422.101(a). An MA plan “must provide enrollees in that plan with coverage of the basic benefits by furnishing the benefits directly or through arrangements, or by paying for the benefits.” 42 C.F.R. § 422.100(a). In providing “basic benefits,” an MAO must comply with national coverage determinations (NCDs) issued by CMS, “[g]eneral coverage guidelines included in original Medicare manuals and instructions unless superseded by operational policy letters or regulations in [part 422] or related instructions; and . . . [w]ritten coverage decisions of local Medicare contractors.” 42 C.F.R. § 422.101(b). At its discretion, an MA plan may also offer additional (or “supplemental”) benefits beyond those covered by original Medicare. 42 C.F.R. § 422.102.

Medically Reasonable and Necessary Medical Services

Part B of the Medicare Act extends coverage to certain types of durable medical equipment (DME) for qualified recipients. 42 U.S.C. § 1395k(a); *id.* § 1395x(s)(6). Not all DME is guaranteed coverage under Medicare Part B, however. The Medicare statute explicitly provides that “no payment may be made under ... Part B of this subchapter for any expenses incurred for items ... [which] are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” *Id.* § 1395y(a)(1)(A); *see also Almy v. Sebelius*, 679 F.3d 297, 299 (4th Cir. 2012).

Medicare coverage of DME is determined in one of three ways. First, Medicare issues a “national coverage determination” (NCD) binding throughout the Medicare system and not subject to review by administrative law judges. *Id.* § 1395ff(f)(1)(B). Second, one of the private insurance carriers with whom Medicare contracts to administer claims under Part B can issue a “local coverage determination” (LCD) “respecting whether or not a particular item or service is covered on an intermediary – or carrier-wide basis.” *Id.* § 1395ff(f)(2)(B); *see also Almy*, 679

F.3d at 299. Finally, if no NCD or LCD is in place, “contractors may make individual claim determinations,” including whether a particular DME meets the statutory requirement of being “reasonable and necessary.” 68 Fed. Reg. 63, 693.

Medicare also has developed guidance in the Medicare Program Integrity Manual (CMS Pub. 100-08) (MPIM), Ch. 13 at § 13.5.1, and the Medicare Benefit Policy Manual (CMS Pub. 100-02) (MBPM), Ch. 15 at § 110 for Medicare contractors applying the “reasonable and necessary” standard.² A device is not “reasonable and necessary” – and thus is not eligible for Medicare coverage – if it is:

- Not “safe” and “effective” – that is, if the device has not “been proven safe and effective based on authoritative evidence” or is not “generally accepted in the medical community as safe and effective for the condition for which it is used”;
- “[E]xperimental” – that is, “investigational”;
- Not “[a]ppropriate” for the individual beneficiary’s needs; or
- “[S]ubstantially more costly than a medically appropriate and realistically feasible alternative pattern of care.”

See also Almy, 679 F.3d at 299; *Int’l Rehabilitative Scis. Inc. v. Sebelius*, 688 F.3d 994, 997 (9th Cir. 2012).

The burden is on the claimant to show that the device is reasonable and necessary. *Almy*, 679 F.3d at 305.

Medicare also instructs contractors as to the type of evidence to be used in making these technical determinations. Such decisions should be based on either “published authoritative evidence” such as “definitive randomized clinical trials” or “general acceptance by the medical community,” with the caveat that “[a]cceptance by individual health care providers” and “limited case studies distributed by sponsors with a financial interest in the outcome[] are not sufficient evidence of general acceptance by the medical community.” MPIM § 13.7.1; *see also Almy*, 679 F.3d at 300.

Statement of the Issues

The issue on appeal is whether the Health Plan is required to pre-approve coverage for Optune (TTFields therapy) for treatment of ██████ glioblastoma.

Analysis

In this appeal, ██████ is seeking pre-approval from the Health Plan for coverage of Optune (TTFields therapy) for treatment of his glioblastoma.

The QIC denied coverage for the therapy at issue stating that:

² ALJs and the Medicare Appeals Council are not bound by CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. 42 C.F.R. § 405.1062(a).

Humana must follow Medicare rules. The rules [LCD L34823] say that tumor treatment field therapy is not reasonable and necessary. (Ex. 1, pg. 4.)

According to the terms of the Health Plan, it provides coverage of services to its members based on the coverage guidelines established by Medicare. (Ex. 2, pg. 28.) Specifically, in order to be covered under the Health Plan, the equipment at issue must be deemed as medically reasonable and necessary under Medicare guidelines. (*Id.*) The Health Plan specifies that in order to be deemed “medically necessary,” services, supplies, or drugs must be “needed for the prevention, diagnosis, or treatment of your medical condition and meet accepted standards of medical practice.” (*Id.*)

After carefully reviewing the evidence submitted and listening to the hearing testimony, this Judge concludes that the Health Plan must pay for the TTFields therapy in question. This Judge is aware that there is a relevant LCD, specifically *NHIC Corp., Local Coverage Determination L34823: Tumor Treatment Field Therapy (LCD L34823) (Oct. 2015)*, which simply states that “Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.” This LCD provides no additional guidelines, criteria for application, or reasoning. This Judge also has reviewed five other LCDs for other jurisdictions in search of further guidelines, however, they provide no additional information. This Judge speculates that the LCDs lack details because the scientific evidence of the effectiveness of this therapy has only recently developed and the LCDs have not yet caught up with recent developments.

Pursuant to 42 C.F.R. § 405.1062, ALJs are not bound by LCDs, but will give substantial deference to these policies if they are applicable to a particular case. Furthermore, if an ALJ declines to follow a policy in a particular case, the ALJ must explain the reasons why the policy was not followed. *See* 42 C.F.R. § 405.1062. An ALJ decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect. *See id.*

Given the lack of information provided by L34823 – and that there is no NCD on this topic – this Judge declines to follow L34823 in this particular case because this Judge finds that the therapy in question has been proven to be safe and effective and is medically reasonable and necessary to treat !
’s condition. This Judge explains his rationale as follows:

Optune (TTFields therapy) Has Been Proven Safe and Effective Based on Authoritative Evidence

Because there is no NCD and the LCD lacks any details or guidelines, this Judge must decide whether Optune (TTFields therapy) has been proven safe and effective based on authoritative evidence. MPIM, Ch. 13 at § 13.5.1; MBPM, Ch. 15 at § 110; *see also Almy*, 679 F.3d at 299. Such decisions should be based on either “published authoritative evidence” such as “definitive randomized clinical trials” or “general acceptance by the medical community,” with the caveat that “[a]cceptance by individual health care providers” and “limited case studies distributed by sponsors with a financial interest in the outcome[] are not sufficient evidence of general acceptance by the medical community.” MPIM § 13.7.1; *see also Almy*, 679 F.3d at 300.

Based on the hearing testimony; medical evidence and studies submitted; and FDA approval of the device, this Judge finds that the therapy in question has been proven safe and effective based on authoritative evidence.

First, this Judge takes into account Dr. Patel's hearing testimony. Dr. Patel is board certified in internal medicine and medical oncology. (Hearing CD.) He testified that he has been treating brain tumors for thirty years. (*Id.*) Dr. Patel stated that recurrent glioblastoma multiforme is considered by the National Institutes of Health as an orphan disease due to its rarity and lack of approved treatment options. (Ex. 3, pg. 5; Hearing CD.) He testified that recent clinical studies of the effect of treating GBM patients with TTFields therapy with Temozolomide have shown significant improvements – approximately 50% – in survival rates. (*Id.*) He stated that the safety and efficacy of TTFields therapy is generally accepted in the medical community. (*Id.*)

Furthermore, Mr. Dan McCoy, [REDACTED] representative who is affiliated with NovoCure, testified that the Health Plan has paid for this therapy for GBM patients in the past. (Hearing CD.) He also testified that there are approximately 230 treatment sites in the country with physicians who are certified to prescribe the therapy in question. (*Id.*)

Second, in addition to studies on TTFields therapy included in the medical record, the Appellant submitted as new evidence results from a phase 3 clinical trial comparing Optune in combination with temozolomide to temozolomide alone in 700 patients with newly diagnosed GBM.³ (Ex. 6, pp. 17-27.)

This Judge may consider new evidence if there is “good cause” for the party to submit the evidence for the first time at this level of review. 42 C.F.R. § 405.1028. This Judge finds that “good cause” exists because the results of this study were only recently released and are very relevant to the issue at hand.

The objective of this study was to evaluate the efficacy and safety of TTFields used in combination with temozolomide maintenance treatment after chemoradiation therapy for patients with glioblastoma. (Ex. 6, pp. 17-27.) The results of this study essentially proved that in 315 patients with glioblastoma who had completed standard chemoradiation therapy, adding TTFields to maintenance temozolomide chemotherapy significantly prolonged progression-free and overall survival. (*Id.*)

After a thorough review of the clinical studies, this Judge finds the studies creditable in establishing the efficacy of TTFields therapy in prolonging and improving the survival of patients diagnosed with GBM.

Finally, this Judge finds that the Optune device is FDA approved, which is further evidence that it is “safe” and “effective.” (Ex. 3, pp. 110-14.) Medicare law states that FDA clearance is *necessary*, but not *sufficient*, for Medicare coverage. *Int'l Rehabilitative Scis. Inc.*, 688 F. 3d at 1002. Specifically, FDA review seeks to determine whether a device is “safe and effective” such

³ Stupp R, Taillibert S, Kanner AA, et al. Maintenance Therapy With Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma: A Randomized Clinical Trial. *JAMA*. 2015;314(23):2535-2543. doi:10.1001/jama.2015.16669. See <http://jama.jamanetwork.com/article.aspx?articleid=2475463>

that it can be marketed to the general public. By contrast, Medicare coverage review seeks to determine whether the device is “reasonable and necessary” for treatment such that the device is worth the government’s money. MBPM, ch. 15, § 110.1; *Int’l Rehabilitative Scis. Inc.*, 688 F.3d at 1002. Therefore, this Judge finds FDA approval to be further evidence of Optune’s safety and effectiveness, but does not find FDA approval to be evidence of the reasonableness and necessity of the therapy for [REDACTED].

Optune (TTFields Therapy) is Medically Reasonable and Necessary to Treat [REDACTED] Condition

This Judge finds Optune (TTFields therapy) to be medically reasonable and necessary for [REDACTED] because it is an appropriate treatment of [REDACTED] condition and there is no medically appropriate and realistically feasible alternative pattern of care for [REDACTED] MPIM, Ch. 13 at § 13.5.1; MBPM, Ch. 15 at § 110.

First, this Judge takes into account the medical record and hearing testimony. The medical record and hearing testimony prove that [REDACTED] is a [REDACTED]-year old gentleman who is diagnosed with GBM. [REDACTED] presented with speech difficulty in July of 2015. (Ex. 3, pp. 2-3; Hearing CD.) An MRI revealed a mass in the left lateral temporal lobe. (*Id.*) On August 10, 2015, he underwent a craniotomy with pathology confirming GBM. (*Id.*) Dr. Patel testified that during the surgery he was able to remove most of the tumor. (*Id.*) Dr. Patel testified that following surgery, most patients relapse, and therefore they are started on radiation therapy with concurrent chemotherapy medication called Temozolomide. (*Id.*) [REDACTED] received five weeks of radiation therapy and is currently taking Temozolomide. (*Id.*)

Dr. Patel stated that [REDACTED] has failed systemic surgery, chemotherapy and all radiotherapy options approved for this clinical scenario. (*Id.*) Therefore, he certified that “there are few if any available options that would benefit the patient in this clinical scenario.” (*Id.*) He certified that “Optune is currently the only chronic treatment option for recurrent glioblastoma that has established its survival benefit and safety profile in a randomized controlled trial against a control arm receiving active effective therapy.” (*Id.*)

This Judge also takes into account the FDA approval letter, which sets forth specific criteria for beneficiaries who would be considered candidates for TTFields therapy delivered by Optune:

This device is indicated for treatment of adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme, following histologically – or radiologically – confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy⁴, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted. (Ex. 3, pg. 110.)

This Judge finds that [REDACTED] meets all the criteria set forth by the FDA.

⁴ This Judge notes that since this FDA approval letter dated April 8, 2011, the FDA has approved Optune in combination with temozolomide for the treatment of adult patients with newly diagnosed GBM. See http://www.abta.org/about-us/news/brain-tumor-news/fda-approves-optune-in_oct15.html

Based on the foregoing evidence, this Judge finds that Optune (TTFields therapy) has been proven to be safe and effective and is medically reasonable and necessary to treat [REDACTED]'s condition.

Conclusions of Law

This Judge concludes that the Health Plan is **required** to pre-approve coverage of Optune (TTFields therapy) (CPT code E0766) for treatment of [REDACTED] glioblastoma pursuant to Medicare Part C provisions of Title XVIII of the Social Security Act and the terms of the Health Plan.

Order

The parties are DIRECTED to comply with this decision.

SO ORDERED.

Dated: DEC 22 2015


Roger Davis
U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, MO

Appeal of: [REDACTED]

ALJ Appeal No.: [REDACTED]

Beneficiary: [REDACTED]

Medicare Part: C

HICN: *****0013A

Before: **Roger Davis**
U.S. Administrative Law Judge

EXHIBIT LIST

EXHIBIT NUMBER	DESCRIPTION	NUMBER OF PAGES
1	Initial, Redetermination & Reconsideration	1-21
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4	Request for Hearing, dated November 25, 2015	1-2
5	OMHA Proceedings	1-19
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7	Waiver of 20-day Advance Written Notice of Hearing	1-5
	Hearing Recording also contains verbal Waiver of 20 Day Notice	

Dated: December 22, 2015

ALJ Appeal No.: [REDACTED]



**Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Miami, Florida**

Appeal of:	OMHA Appeal No.: 1-7872832118
Enrollee: ;	Medicare: Part C
Medicare No.: *****7938A	Before: Gerald Wayne Hynum Administrative Law Judge

DECISION
FAVORABLE

After careful consideration of the evidence in the record and the arguments presented in the hearing, a favorable decision is entered for ("Appellant").

Procedural History

This case is before the Administrative Law Judge ("ALJ") on appeal from an unfavorable decision made by Humana Insurance Company ("Humana"), the beneficiary's Medicare Health Management Organization and Maximus Federal Services, Medicare Manage Care & PACE Reconsideration Project (Maximus) (Ex. 1). In its reconsideration dated August 25, 2018, Maximus agreed that Humana did not have to pay for the tumor treatment field therapy (TTFT) (Optune™) (E0766) provided to enrollee on April 19, 2018. (Ex. 1, pp. 3-7)

Appellant timely filed a request for an ALJ hearing that was received by the Office of Medicare Hearings and Appeals ("OMHA") on September 11, 2018. (Ex. 3) The remaining amount in controversy meets the jurisdictional requirements for a hearing before OMHA.¹ Therefore, the jurisdictional predicates are met and the claim for services which is covered by this decision is properly before the ALJ for *de novo* review.

Appellant has been properly notified at the redetermination and reconsideration levels of this appeal that the regulations require full and early presentation of the evidence, and that additional evidence may not be submitted to the ALJ unless good cause is shown.² New evidence was submitted by Appellant's representative Novocure Ltd. Since the limitation on the submission of new evidence is not applicable to Part C appeals, the documentation received from Appellant was admitted into the record as Exhibit 5. See 42§§422.562(d) (2) (vi)

¹ 81 Fed. Reg. 65651 (September. 23, 2016)

² 42 CFR §§405.1018 and 405.1028

OMHA Appeal No. 1-7872832118

A telephone hearing was held on November 15, 2018. Julie Miles, RN Clinical Appeals Specialist from Novocure Ltd, represented the enrollee and knowingly waived the right to legal counsel. (Hearing CD). Present from Novocure Ltd were also Dan Mc Coy Case Manager and Timothy Park, RN who did not testified. Present at the hearing and testifying for Humana were: Dr. Bryan Carr, and Marcia Taylor Grievance and Appeals Specialist. The exhibits were admitted without objections.

After a thorough review of the record and testimony presented at the hearing, the ALJ concludes that Humana does have to pay for Optune™ treatment provided to enrollee on April 19, 2018.

Issues

1. Whether the contract coverage provisions have been met warranting payment?

Findings of Fact

1. The beneficiary, a 38 year old female, was diagnosed with a WHO grade IV glioblastoma multiforme involving the right frontal and parietal lobes, status post craniotomy with tumor resection. (Ex. 2, pp. 1, 7-8, 19-99) She completed adjuvant right front brain radiation therapy and Optune TTF therapy. By 06/07/2016, recurrent glioma was detected confirmed by an MRI. She underwent resection. She continued to take Temodar oral chemotherapy and also utilized Optune TTF therapy. An MRI from 03/05/2018 showed the disease as stable and unchanged from 11/14/2017 MRI. The physician's opined that "[o]verall, we are very pleased with her lack of recurrent symptoms and favorable MRI brain. We recommended continuing current Optune therapy alone with Temodar systemic therapy..." (*Id.* at 8)

2. The record contains Dr. Phuong-Di prescription orders for Optune for the diagnosis of Malignant Neoplasm of Frontal lobe, these orders were signed on 10/01/2016, 11/02/2016, 10/18/2017, 04/05/2018, and 05/02/2018. (*Id.* at 6, 16-18)

3. Humana denied coverage for the Optune treatment provided on 04/19/2018. (Ex. 1, pp. 12, 21-22) The member appealed. (*Id.* 3-5, 12) Humana affirmed the denial and forward the case to the IRE.

4. On 08/25/2018, the QIC affirmed Humana's denial. (Ex. 1, pp. 3-7)

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services ("HHS"), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner.³

³ Social Security Act (Act) § 1869(b)(1)(A)

OMHA Appeal No. 1-7872832118

In implementing this statutory directive, the Secretary has delegated her authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA.⁴ The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council.⁵

A hearing before an ALJ is only available if the remaining amount in controversy is \$100 or more.⁶ The request for hearing is timely if filed within sixty days after receipt of the notice of the QIC's reconsideration decision.⁷

B. Scope of Review

Under the implementation policy of the Centers for Medicare and Medicaid Services ("CMS"), United States Department of Health and Human Services ("HHS"), all Medicare Part B claims which have been issued a reconsideration by a Qualified Independent Contractor ("QIC") are governed by the ALJ Hearing Procedures outlined in 42 C.F.R. §§ 405.1000 et seq.⁸

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in [the Appellant's] favor. However, if evidence presented before the hearing causes the ALJ to question a favorable portion of the determination, he or she will notify [the Appellant] before the hearing and may consider it an issue at the hearing.⁹

The ALJ may decide a case on the record and not conduct an oral hearing if the appellant and all the parties indicate in writing that they do not wish to appear before the ALJ at an oral hearing or if the evidence in the hearing record supports a finding in favor of the appellant on every issue.¹⁰

C. Standard of Review

The [Office of Medicare Hearings and Appeals] is staffed with Administrative Law Judges who are appointed pursuant to the Administrative Procedure Act. They act as independent finders of fact in conducting hearing pursuant to §1869 of the Act. ALJs conduct "*de novo*" hearings of the facts and law. See 70 Fed. Reg. 36386 (June 23, 2005).

II. Legal Authority Binding on ALJs

An ALJ is bound only by statutes enacted by Congress, regulations issued under the Act, rulings issued by CMS, and national coverage decisions in effect during the period at issue.¹¹ An ALJ should consider, but is not bound by, any other policy statements, instructions, and guides

⁴ See 70 Fed. Reg. 36386, 36387 (June 23, 2005)

⁵ *Id.*

⁶ See CMS Rul. 02-1, 67 Fed. Reg. 62478, 62480 (Oct. 7, 2002); 70 Fed. Reg. 11420, 11423 (Mar. 8, 2005); 72 Fed. Reg. 73348 (Dec. 27, 2007)

⁷ 42 C.F.R. § 405.1002(a)

⁸ 70 Fed. Reg. 11424 (March 8, 2005)

⁹ 42 C.F.R. § 405.1032

¹⁰ 42 C.F.R. § 405.1038

¹¹ 42 CFR §405.1060

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issued by CMS or by any Local Medical Review Policy or Local Coverage Determination.¹² While not binding on the ALJ, however, these manual and policy sections are entitled to substantial deference.¹³

III. Principles of Law

A. Statutes and Regulations- Medicare Advantage Program

The Medicare Advantage (MA) Program, Part C of the Title XVIII of the Act, provides that a MAO offering a MA plan must provide enrollees, at a minimum, with all basic Medicare-covered services by furnishing the benefits directly or, through arrangements, by paying for the benefits. MAOs may also provide mandatory and supplemental benefits through their plans. See §1852(a) of the Act.

Title 42 of the Code of Federal Regulations, Part 422 provides the rules and regulations that govern the MA Program. Pursuant to 42 C.F.R. §422.100(c), a "MA plan includes at a minimum basic benefits, and also may include mandatory and optional supplemental benefits." 42 C.F.R. §422.101(a) indicates that each MAO must "[p]rovide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B) and that are available in the plan's service area. Services may be provided outside of the service area of the plan if the services are accessible and available to enrollees."

Pursuant to 42 C.F.R. §422.111, a MAO must disclose to each enrollee electing a MA plan it offers, in a clear, accurate, and standard form, and at the time of enrollment and at least annually thereafter, the detailed content of plan description, including, but not limited to, the plan's service area, benefits, access, out-of-area coverage, emergency coverage, supplemental benefits, prior authorization and review rules, grievance and appeal procedures, quality improvement programs, disenrollment rights, and catastrophic caps and single deductibles, and premiums and cost-sharing, such as co-payments, deductibles and coinsurance.

Under section 1832(a) of the Act, Medicare Part B benefits include "medical and other health services." Section 1861(s) (6) defines "medical and other health services" as including DME. Section 1861(n) lists certain items that are classified as DME such as iron lungs, oxygen tents, hospital beds, wheelchairs, blood-testing strips and blood glucose monitors for individuals with diabetes, and seat-lift chair.

DME is defined as equipment which (1) can stand repeated use; (2) is primarily and customarily used to serve a medical purpose; (3) is generally not useful to a person in the absence of illness or injury; and (4) is appropriate for use in the home.¹⁴

¹² 42 CFR §405.1062

¹³ *Id.*; *Lyng v. Payne*, 476 U.S. 926, 939 (1986).

¹⁴ 42 CFR §414.202

OMHA Appeal No. 1-7872832118

B. Policy and Guidance

42 C.F.R. §422.101(b) provides that each MAO must also comply with CMS' national coverage determinations (NCDs), general coverage guidelines included in Medicare manuals and instructions, and written coverage decisions of local Medicare contractors with jurisdiction for claims in the geographic area in which services are covered under the MA plan. An ALJ is bound only by statutes enacted by Congress, regulations issued under the Act, rulings issued by CMS, and national coverage decisions in effect during the period at issue. *See* 42 C.F.R. §§ 405.1060, 405.1062. Pursuant to § 1869 (b)(3)(A) of the Act, and codified at 42 C.F.R. § 405.8 an Administrative Law Judge may not disregard, set aside, or otherwise review a National Coverage Determination (NCD).

CMS Medicare Benefit Policy Manual (MBPM), CMS Pub. 100-02, Ch. 15, § 110.1. provides in part as follows:

C. Necessary and Reasonable

Although an item may be classified as DME, it may not be covered in every instance. Coverage in a particular case is subject to the requirement that the equipment be necessary and reasonable for treatment of an illness or injury, or to improve the functioning of a malformed body member. These considerations will bar payment for equipment which cannot reasonably be expected to perform a therapeutic function in an individual case or will permit only partial payment when the type of equipment furnished substantially exceeds that required for the treatment of the illness or injury involved.

In addition, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local medical review policies ("LMRPs") or local coverage determinations ("LCDs"). The applicable LCD is L34823 for Tumor Treatment Field Therapy effective on or after January 1, 2017.

D. Financial Liability

Medicare policy states that the financial liability protection "...provisions apply to individuals enrolled in the Medicare Fee-For-Service (FFS) program (Parts A and B), but are not applicable to Medicare M+C (Part C) enrollees nor to non-Medicare enrollees.

Analysis

The Appellant, a 38 year old female, is requesting that her Medicare Advantage Plan (the "Plan") be required to cover her Optune tumor field therapy treatment for her glioblastoma brain cancer. The Plan is required at a minimum to provide coverage for all services and benefits that are covered by original Medicare. 42 CFR Sec. 422.100(a). The Plan may also provide its enrollees with supplemental benefits. 42 CFR Sec. 422.102. In this appeal the Plan's Evidence of Coverage (Ex. 1) does not provide for any supplemental benefits that are applicable to this appeal. Therefore, the issue in this appeal is whether original Medicare would cover the subject Optune therapy for treatment of the Appellant's glioblastoma. This Judge is required to follow National Coverage Determinations (NCDs) promulgated by the Secretary. 42 CFR Sec. 405.1060. However, there are no NCDs applicable to this appeal. This Judge is not bound by Local Coverage Determinations

OMHA Appeal No. 1-7872832118

(LCDs) regarding the subject treatment, but he is required to give LCDs substantial deference, and to explain the reasons for a departure from the LCD. 42 CFR 405.1062(a)(b)

The LCD applicable to this appeal and to tumor field therapy in general is L34823 which states "Tumor field therapy (E0766) will be denied as not reasonable and necessary." Other than boilerplate general guidelines applicable to all claims, neither the LCD nor the companion Policy Article (A52711) state why tumor field therapy claims should be denied other than to say it is "not reasonable and necessary." The first issue to be decided then, is whether this Judge is bound by the aforementioned LCD because if he is so bound that would compel the Judge to automatically enter an Unfavorable Decision in this appeal no matter how favorable the evidence is in favor of the Appellant. This Judge is aware that the Medicare Appeals Council has entered a recent decision¹⁵ which found that Administrative Law Judges are bound by the LCDs when the Medicare coverage at issue is furnished by a Part C carrier, *i.e.*, a Medicare Advantage Plan. This Judge respectfully disagrees. The Council found that since MA Plans are required to follow the LCDs, the ALJs should also be required to follow the LCDs in cases involving an MA Plan. However, there is a regulation which specifically states that ALJs are not bound by LCDs, but will give substantial deference to LCDs. 42 CFR Sec. 405.1062(a) The Code of Federal Regulations is law that must be followed unless and until the regulation is changed via the statutory process. To say that an ALJ is bound by the LCDs when an MA Plan provides the Medicare coverage, would be a modification of 42 CFR Sec. 405.1062 (a) and neither this Judge, nor the Appeals Council, has the authority to modify or depart from the Code of Federal Regulations. There is no statute or regulation which states that ALJs are bound by the LCDs if an MA Plan is providing the coverage. Only a United States statute, or other regulation in the Code of Federal Regulations that supersedes or limits the applicability of 42 CFR Sec. 405.1062(a) could require that ALJs and the Council are bound by an LCD in MA Plan cases, and there is no such statute or regulation.

The above referenced Appeals Council decision also stated that neither an ALJ nor the Council has the authority to review the validity of an LCD for purposes of a claim appeal. 42 CFR Sec. 405.1062(c) However, an ALJ departing from an LCD in a particular appeal is not the same as an ALJ setting aside, or reviewing the validity of an LCD. A challenge to the validity of a particular LCD and/or a request to set aside a particular LCD has a separate process, commenced by an acceptable LCD complaint, 42 CFR Sec. 426.300(a) that is distinct and separate from the appeal of a particular claim where the ALJ may or may not follow the LCD. 42 CFR Sec. 426.310(a) This Judge understands that an MA Plan is required to follow the LCDs, so therefore the MA Plan is not at fault for denying this claim. However, now that the claim is before an ALJ who has the authority to depart from the LCD if the evidence and facts warrant it, there is no valid reason to automatically follow the LCD just because the Plan was required to do so. There is no dispute that an ALJ has the authority to depart from an LCD under original Medicare, if the facts warrant the departure. There is also no dispute that the MA Plan is required to cover all services and benefits covered by original Medicare. So if an ALJ can depart from an LCD in an original Medicare appeal, but cannot depart from the LCD in an MA Plan appeal, then the MA Plan enrollee is not getting the same services and benefits as the original Medicare beneficiary contrary to the requirements of 42 CFR 100(a). This Judge therefore finds that he has the authority to depart from LCD L34823 if the facts and evidence support the departure, and providing that the Judge explains the reasons why the LCD is not being followed.

¹⁵ In Re Blue Cross Blue Shield of Western New York, Medicare Appeals Council M-17-6134 (March 1, 2018).

OMHA Appeal No. 1-7872832118

In this particular appeal, this Judge finds that he should depart from LCD L34823 because L34823 states that tumor field therapy should be denied because it is not reasonable and necessary. However, in the appeal *sub judice*, the overwhelming weight of the evidence shows that in this particular case, the Optune tumor field therapy is reasonable and necessary for the safety and well-being of the Appellant, and the subject therapy is reasonable and necessary to treat and alleviate the symptoms of the Appellant's brain cancer glioblastoma and to delay and/or prevent the death of the Appellant. Since LCD L34823 is predicated upon a finding that the tumor field therapy is not reasonable and necessary in general, it does not apply to this particular Appellant since the evidence clearly shows that the treatment is reasonable and necessary for this particular patient. This Judge therefore finds that he should depart from LCD L34823 in this particular appeal. The fact that this Judge is departing from the LCD in this particular appeal does not mean that the Judge has found the LCD to be unreasonable or invalid. It is simply not applicable to the facts of this particular appeal.

The Optune field therapy treatment was approved by the FDA in 2015 for newly diagnosed glioblastoma in combination with Temozolomide after standard surgical reduction and radiation therapy. The evidence in this appeal shows that in April of 2018, (the dates of service at issue) tumor field therapy was the standard of care for patients with glioblastoma following surgical reduction and radiation. The Appellant completed her radiation treatments in 2016. On 06/07/2016, recurrent glioma was detected on an MRI and the Appellant underwent an open craniotomy and resection of the tumor on 06/27/2016. The Appellant's physician has also prescribed Temodar (the trade name for Temozolomide) in conjunction with the Optune therapy. The Appellant therefore meets the FDA guidelines for the Optune Tumor Field Therapy. The evidence also shows that the Appellant has been receiving periodic Optune therapy since March of 2016, and the Plan paid for the Optune treatment since March of 2016, up until the current denial. Glioblastoma is the most aggressive malignant primary brain tumor in humans, and it is very difficult to treat. Median survival for patients with glioblastoma is only 14 months. Only 10% of glioblastoma patients live a year. The Appellant on the other hand has survived over two and a half years since the discovery of the tumor due in large part to the Optune and Temodar therapy she has been receiving. The Optune therapy has also provided the Appellant with a higher quality of life during that period. The medical record in this appeal has shown that the Optune therapy has been safe and effective for the Appellant, and it has prolonged her life. The Appellant has submitted several studies which show the safety and efficacy of the Optune therapy, which corroborates the positive results the Appellant has received from the subject therapy. The evidence is clear that the Optune tumor field therapy has been, and is, reasonable and necessary for this particular Appellant. Medicare coverage requirements are met for the dates of service at issue, and the MA Plan is directed to provide coverage for the Optune therapy provided to the Appellant on April 19, 2018.

Conclusion

It is the decision of the ALJ that Humana has to cover the tumor treatment field therapy (TTFT) (Optune™) (E0766) provided to enrollee on April 19, 2018.

OMHA Appeal No. 1-7872832118

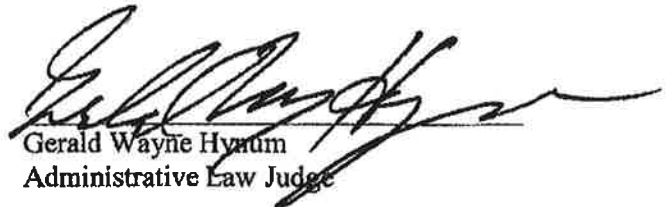
Order

The QIC's decision is hereby **REVERSED** and the Medicare contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED

Dated:

DEC 11 2018


Gerald Wayne Hynum
Administrative Law Judge

GWH: sm



**Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Miami, Florida**

Appeal of: Enrollee: Medicare No.: *****7938A	OMHA Appeal No.: 1-7872832118 Medicare: Part C Before: Gerald Wayne Hynum Administrative Law Judge
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EXHIBIT LIST

EXHIBIT NUMBER	DESCRIPTION	PAGE NUMBERS
1	Organization Determination, MAO Reconsideration and Part C QIC Reconsidered Decision Procedural Documents	1-314
2	Medical Records/Evidence received by MAO and CMS contractors	1-105
3	Request for ALJ Hearing	1-4
4	OMHA Proceedings	1-28
5	New Evidence by Novocure	1-14

Dated: **DEC 11 2018**



Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

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October 14, 2016

ALJ Appeal Number: 1-4878968650

Appellant: - - -

NOVOCURE
95 COMMERCE WAY
PORTSMOUTH, NH 03801

NOTICE OF DECISION

Enclosed is the Administrative Law Judge's decision for the above case. As explained below, the decision is binding unless it is appealed to the Medicare Appeals Council, or the Medicare Appeals Council reviews the case on its own motion.

This decision is based on the administrative record and any testimony presented to the Administrative Law Judge for the matter at issue. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. Other parties may also appeal the decision. In addition, the Medicare Appeals Council may decide to review the decision on its own motion. If you or another party does not appeal the decision, and the Medicare Appeals Council does not review the decision, the decision is binding on all parties and you and the other parties will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing. Your appeal must identify the parts of the decision that you disagree with,

and explain why you disagree. You can do this by completing the enclosed *Request for Review* (Form DAB-101), or by writing a letter containing the following:

- The enrollee's name;
- The enrollee's health insurance claim number;
- The item(s) or service(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided;
- The date of the ALJ's decision; and
- Your name and signature, and, if applicable, the name and signature of your representative.

Mail your appeal and a copy of the enclosed decision to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Or, you may fax your appeal to the Medicare Appeals Council at (202) 565-0227. If you send a fax, please **do not** also mail a copy.

You must always send a copy of your request for review to the other parties who received a copy of this decision.

How much time do I have to file an appeal?

The Medicare Appeals Council must receive your written appeal **within 60 days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

Additional information about filing an appeal with the Medicare Appeals Council is available at <http://www.hhs.gov/dab/>. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or 1-866-365-8204 (toll-free), if you have questions about filing an appeal.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to the Administrative Law Judge for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll free phone number and mailing address are at the top of this notice.

Copies were sent to the following parties and Medicare Contractors:

ANITA RAMSEY
XEROX ACS ATTN: DEMETRA
CHRISTOPHER
2432 FORTUNE DRIVE #120
LEXINGTON, KY 40509

HUMANA INSURANCE COMPANY
1100 EMPLOYERS BLVD
DePERE, WI 54115

Maximus Federal Services, Inc.
3750 Monroe Avenue, Suite #702
Pittsford, NY 14534-1302

Enclosures:

Form DAB-101, Request for Review



**Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, Missouri**

Appeal of:

ALJ Appeal No.: **1-4878968650**

Enrollee:

Medicare Part: **C**

HICN: *

Before: **Thomas C. Strafuss**
U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, a **FAVORABLE** decision is entered for Appellant/Enrollee ("Enrollee"), .

PROCEDURAL HISTORY

Enrollee disputes the decision of Humana, a Medicare Advantage ("MA") plan, to deny approval of payment for tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment provided through Optune, an out of network supply store. On August 6, 2016, Humana reexamined Enrollee's request for reimbursement for tumor treatment field therapy and affirmed the initial denial. (Exh. 2, p. 96) On August 10, 2016, MAXIMUS Federal Services, a Qualified Independent Contractor ("QIC"), evaluated the claim and issued a decision upholding Humana's decision on the same grounds. (Exh. 1, p. 3)

The Office of Medicare Hearings and Appeals ("OMHA") received Enrollee's timely request for a hearing on August 19, 2016. The requested hearing was held via telephone on October 5, 2016. The Appellant sent in a letter on his own behalf. Dan McCoy appeared telephonically on behalf of Novocure. Cynthia McCloud and Bruce Niebylski, M.D., appeared telephonically on behalf of Humana. The entire case file was admitted into the record without objection.

ISSUE

Whether or not the plan coverage provisions have been met and whether or not payment is warranted.

FINDINGS OF FACT

The following facts were established by a preponderance of the evidence:

1. Enrollee, a male, has been diagnosed with glioblastoma multiforme of the brain (ICD-10 code: C71.9). (Exh. 2, pp. 3-16) Enrollee is now requesting approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment provided through Optune, an out of network supply store. (*Id.*)
2. Enrollee was enrolled in a Humana Medicare Employer PPO Plan. (Exh. 1, p. 31)
3. On June 20, 2016, Humana denied Enrollee's request for approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment and affirmed that decision in redetermination. (Exh. 1, p. 12; Exh. 2, p. 96) Humana's reason for denial was that Local Coverage Determination ("LCD") L34823 regarding tumor treatment field therapy states that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. (*Id.*)
4. On August 10, 2016, the QIC examined Enrollee's claim and affirmed Humana's denial of coverage. (Exh. 1, p. 3)

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

An individual or an organization who is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services ("HHS") provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. The Social Security Act (the Act), Title XVIII, section 1869(b)(1)(A); *see* 42 C.F.R. § 405.1014. In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to the Office of Medical Hearings and Appeals ("OMHA"). *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005). The Administrative Law Judges ("ALJ") within OMHA issue the final decisions of the Secretary unless later reviewed by the Medicare Appeals Council. *Id.*

For requests filed in calendar years 2010 through 2012, the minimum amount remaining in controversy required for an ALJ hearing is \$130.00 (following application of any co-insurance or deductible), \$140.00 for calendar years 2013 and 2014, and, beginning January 1, 2015, \$150.00. *See* § 1869(b)(1)(E) of the Act, 74 Fed. Reg. 48976 (Sept. 2, 2009), 77 Fed. Reg. 59619 (Sept. 28, 2012), 42 C.F.R. § 405.1006(b), and 42 C.F.R. § 405.1006(d)(1)(ii).

To be considered timely, the request for hearing must be received by OMHA within sixty days after an appellant receives the QIC's reconsideration decision. An appellant is presumed to have received the QIC's reconsideration five days after the date noted on the first page of the reconsideration unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3).

In this case, Appellant timely requested a hearing before an ALJ. 42 C.F.R. § 405.1014. The remaining amount in controversy meets the jurisdictional requirements for a hearing. 42 C.F.R. § 405.1006.

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in the appellant's favor. 42 C.F.R. § 405.1032. However, if evidence presented before or during the hearing causes the ALJ to question a fully favorable decision, he or she will notify the appellant and will consider it an issue at the hearing. *Id.*

An ALJ may issue a decision on the record on his or her own initiative if the evidence in the hearing record supports a fully favorable finding. 42 C.F.R. §§ 405.1000(g) and 405.1038(a). In addition, if all parties to the hearing waive their right to appear at the hearing, the ALJ may make a decision based on the evidence that is in the record and any new evidence that is admitted by the ALJ. 42 C.F.R. § 405.1000(e).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue. 42 C.F.R. § 405.1000(d) and Section 557 of the Administrative Procedures Act. A *de novo* review requires the ALJ to review and evaluate the evidence without regard to the findings in the prior determinations on the claim and make an independent assessment in reliance upon the evidence and controlling laws. All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Act and applicable implementing regulations, are binding on the ALJ. 42 C.F.R. § 405.1063.

An appellant has the burden of proving each element of a Medicare claim by a preponderance of the evidence (satisfied through the submission of sufficient evidence in accordance with Medicare rules). *See* Sections 1814(a)(1), 1815(b), and 1833(e) of the Act; *see also* 42 C.F.R. §§ 424.5(a)(6), 405.1018, 405.1028, and 405.1030.

II. Principles of Law

The Medicare program, Title XVIII of the Social Security Act, is administered through the Centers for Medicare and Medicaid Services, a component of the United States Department of Health and Human Services ("HHS"). Title XVIII, §1832 of the Act describes the scope of benefits provided for by Medicare and provides that those benefits shall include "medical and other health services." In addition, section 1862(a)(1)(A) of the Social Security Act provides for coverage and payment for those services and supplies only when those services or supplies are considered to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

The obligations of a Medicare Advantage (“MA”) Organization to its enrollees are set forth in §1852 of the Act. 42 C.F.R. §422 establishes standards, requirements, limitations, and procedures for Medicare services furnished or paid for via MA plans. Pursuant to 42 C.F.R. §422.100, MA Organizations must provide their members with the same benefits provided under Parts A and B of Medicare. According to 42 C.F.R. § 422.111, MA Organizations are required to make certain disclosures to its enrollees regarding its services and benefits. These disclosures include the plan’s service area, benefits, and exclusions from coverage. *Id.*

Local Coverage Determination (“LCD”) L34823 regarding tumor treatment field therapy states:

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

ANALYSIS

Enrollee, _____, has been diagnosed with glioblastoma multiforme of the brain (ICD-10 code: C71.9). (Exh. 2, pp. 3-16) Enrollee is now requesting approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment provided through Optune, an out of network supply store. (*Id.*) Enrollee was enrolled in a Humana Medicare Employer PPO Plan. (Exh. 1, p. 31)

On June 20, 2016, Humana denied Enrollee’s request for approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment and affirmed that decision in redetermination. (Exh. 1, p. 12; Exh. 2, p. 96) Humana’s reason for denial was that Local Coverage Determination (“LCD”) L34823 regarding tumor treatment field therapy states that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. (*Id.*) On August 10, 2016, the QIC examined Enrollee’s claim and affirmed Humana’s denial of coverage. (Exh. 1, p. 3)

The obligations of a Medicare Advantage (“MA”) Organization to its enrollees are set forth in §1852 of the Act. 42 C.F.R. §422 establishes standards, requirements, limitations, and procedures for Medicare services furnished or paid for via MA plans. Pursuant to 42 C.F.R. §422.100, MA Organizations must provide their members with the same benefits provided under Parts A and B of Medicare.

The Medicare Contractor CGS Administrators, LLC, created a Local Coverage Determination addressing the issue in this case. That LCD simply states that tumor treating fields therapy will be denied as not reasonable and necessary. There is no additional detail or guidance contained within the LCD. The only substance is a reference section entitled “Sources of Information and Basis for Decision.” That section lists seventeen separate citations which presumably support the summary conclusion that tumor treating fields therapy is not reasonable and necessary. The list is noteworthy in that the most recent citation is from 2013.

Pursuant to section 1869(f)(2) of the Act, Administrative Law Judges are to give substantial deference to Local Coverage Determinations. If an ALJ does not follow an applicable LCD, an explanation must be given. The ALJ chooses to deviate from the LCD for the following reasons.

Tumor treating fields therapy using an electric stimulation device is FDA approved. FDA approval necessarily means the treatment has been deemed safe and effective. The most recent phase three clinical trial,¹ published in December 2015 shows that this treatment is effective because it significantly prolongs the disease progression of glioblastoma and increases the overall odds of survival. The 2015 study is given greater weight than the LCD both because it is recent proof of efficacy and because the LCD lacks any substantive guidance. Finally, the Enrollee suffers from glioblastoma. Dr. Mohamed Hamza wrote a letter in support of tumor treating field therapy for the Enrollee, and believed that the tumor treatment therapy, in combination with temozolomide, is the most appropriate option for his care. Therefore the ALJ concludes that tumor treating field therapy was medically reasonable and necessary in this case, and Medicare covers this service.

Subsequently because Medicare Parts A and B will cover the tumor treatment field therapy at issue then Humana is required to cover the services as well.

The undersigned concludes that Medicare coverage is available for the tumor treatment field therapy requested by the Enrollee. The services requested are covered under Medicare Parts A or B and thus Medicare Part C coverage must be approved.

CONCLUSIONS OF LAW

The undersigned concludes Humana does have to cover tumor treatment field therapy requested by the Enrollee.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim herein in accordance with this decision.

OCT 14 2016

SO ORDERED

Dated: _____


Thomas C. Strafuss

U.S. Administrative Law Judge

¹ Stupp R., Taillibert S., Kanner A., et al. Maintenance Therapy With Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma: A Randomized Clinical Trial. *JAMA*. 2015; 314(23): 2535-2543. Doi:10.1001/jama.2015.16669. See <http://jama.jamanetwork.com/article.aspx?articleid=2475463>. (Exh. 2, p. 17)

REQUEST FOR REVIEW OF ADMINISTRATIVE LAW JUDGE (ALJ) MEDICARE DECISION / DISMISSAL

1. APPELLANT (the party requesting review)

2. ALJ APPEAL NUMBER (on the decision or dismissal)

3. BENEFICIARY*

4. HEALTH INSURANCE CLAIM NUMBER (HICN)*

*If the request involves multiple claims or multiple beneficiaries, attach a list of beneficiaries, HICNs, or other information to identify all claims being appealed.

5. PROVIDER, PRACTITIONER, OR SUPPLIER

6. SPECIFIC ITEM(S) OR SERVICE(S)

7. Medicare claim type: ☐ Part A ☐ Part B ☐ Part C - Medicare Advantage
☐ Part D - Medicare Prescription Drug Plan ☐ Entitlement/enrollment for Part A or Part B

8. Does this request involve authorization for an item or service that has not yet been furnished?

☐ Yes

If Yes, skip to Block 8.

☐ No

If No, Specific Dates of Service:

9. If the request involves authorization for a prescription drug under Medicare Part D, would application of the standard appellate timeframe seriously jeopardize the beneficiary's life, health, or ability to regain maximum function (as documented by a physician) such that expedited review is appropriate? ☐ Yes ☐ No

I request that the Medicare Appeals Council review the ALJ's ☐ decision or ☐ dismissal order [check one] dated _____. I disagree with the ALJ's action because (specify the parts of the ALJ's decision or dismissal you disagree with and why you think the ALJ was wrong):

(Attach additional sheets if you need more space)

PLEASE ATTACH A COPY OF THE ALJ DECISION OR DISMISSAL ORDER YOU ARE APPEALING.

DATE			DATE		
APPELLANT'S SIGNATURE (the party requesting review)			REPRESENTATIVE'S SIGNATURE (include signed appointment if not already submitted.)		
PRINT NAME			PRINT NAME		
ADDRESS			ADDRESS		
CITY, STATE, ZIP CODE			CITY, STATE, ZIP CODE		
TELEPHONE NUMBER	FAX NUMBER	E-MAIL	TELEPHONE NUMBER	FAX NUMBER	E-MAIL

(SEE FURTHER INSTRUCTIONS ON PAGE 2)

If you have additional evidence, submit it with this request for review. If you need more time, you must request an extension of time in writing now, explaining why you are unable to submit the evidence or legal argument now.

If you are a provider, supplier, or a beneficiary represented by a provider or supplier, and your case was reconsidered by a Qualified Independent Contractor (QIC), the Medicare Appeals Council will not consider new evidence related to issues the QIC has already considered unless you show that you have a good reason for submitting it for the first time to the Medicare Appeals Council.

IMPORTANT: Include the HICN and ALJ Appeal Number on any letter or other material you submit.

This request must be received within 60 calendar days after you receive the ALJ's decision or dismissal, unless we extend the time limit for good cause. We assume you received the decision or dismissal 5 calendar days after it was issued, unless you show you received it later. If this request will not be received within 65 calendar days from the date on the decision or dismissal order, please explain why on a separate sheet.

You must file your request for review in writing with the Medicare Appeals Council at:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

You may send the request for review by U.S. Mail, a common carrier such as FedEx, or by fax to (202) 565-0227. If you send a fax, please do not also mail a copy. **You must send a copy of your appeal to the other parties and indicate that all parties, to include all beneficiaries, have been copied on the request for review. For claims involving multiple beneficiaries, you may submit a copy of the cover letters issued or a spreadsheet of the beneficiaries and addresses who received a copy of the request for review.**

If you have any questions about your request for review or wish to request expedited review of a claim involving authorization of your prescription drug under Medicare Part D, you may call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100. You may also visit our web site at www.hhs.gov/dab for additional information on how to file your request for review.

PRIVACY ACT STATEMENT

The collection of information on this form is authorized by the Social Security Act (section 205(a) of title II, section 702 of title VII, section 1155 of Title XI, and sections 1852(g)(5), 1869(b)(1), 1871, 1872, and 1876(c)(5)(B) of title XVIII, as appropriate). The information provided will be used to further document your claim. Information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your claim. Information you furnish on this form may be disclosed by the Department of Health and Human Services or the Social Security Administration to another person or governmental agency only with respect to programs under the Social Security Act and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services, the Social Security Administration, or other agencies.



**Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, MO**

Appeal of:

ALJ Appeal No.: **1-4878968650**

Beneficiary:

Medicare: **Part C**

HICN: *

Before: **Thomas Strafuss**
Administrative Law Judge

EXHIBIT LIST

EXHIBIT NUMBER	DESCRIPTION	PAGE NUMBERS
1	Organization Determination, MAO Reconsideration and Part C QIC Reconsidered Decision Procedural Documents	314
2	Medical Records/Evidence received by MAO and CMS contractors	139
3	Request for ALJ Hearing	2
4	OMHA Proceedings	46

Dated: 10/6/2016



Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

Kansas City Field Office
601 East 12th Street, Suite 221
Kansas City, MO 64106
816-599-3300 (Main)
816-599-3290 (ALJ Woodyard Team)
816-527-0115 (FAX)
844-566-6258 (Toll Free)

Date: January 9, 2017

ALJ Appeal Number: 1-5309926775

Appellant:

ATTN: JORGE MORALES
195 Commerce Way
Portsmouth, NH 03801

NOTICE OF DECISION

Enclosed is the Administrative Law Judge's decision for the above case. As explained below, the decision is binding unless it is appealed to the Medicare Appeals Council, or the Medicare Appeals Council reviews the case on its own motion.

This decision is based on the administrative record and any testimony presented to the Administrative Law Judge for the matter at issue. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. In addition, you may file either an oral or written Request for an Expedited Review with the Medicare Appeals Council if your appeal involves a coverage determination, is not solely a request for payment of a Part D drug already furnished, and your prescribing physician or other prescriber indicates, or the Medicare Appeals Council determines, that the standard time frame for rendering a decision may seriously jeopardize your life, health or ability to regain maximum function.

The Medicare Appeals Council may also decide to review the decision on its own motion. If you do not appeal the decision and the Medicare Appeals Council does not review the decision, the decision is binding and you will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.

How do I file an appeal if I want an expedited review?

You may request that your claim be expedited by calling the Medicare Appeals Council at (202) 565-0100 or 1-866-365-8204 (toll-free). An expedited review will be granted only if your appeal involves a coverage determination, is not solely a request for payment of a Part D drug already furnished, and your prescribing physician or other prescriber indicates, or the Medicare Appeals Council determines, that the standard time frame for rendering a decision may seriously jeopardize your life, health or ability to regain maximum function.

How much time do I have to file an appeal?

The Medicare Appeals Council must receive your appeal **within 60 days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

Additional information about filing an appeal with the Medicare Appeals Council is available at <http://www.hhs.gov/dab/>. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or 1-866-365-8204 (toll-free), if you have questions about filing an appeal.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing, unless it is an oral Request for an Expedited Review. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree.

You may submit your request for review using one of three available methods: mail, fax, or electronic file (E-File). **Please do not submit your request for review using more than one method.** Regardless of how you file your appeal, **you must always send a copy of your request for review to the other parties who received a copy of this decision.**

By mail:

You can do this by completing the enclosed *Request for Review* (Form DAB-101), or by writing a letter containing the following:

- The enrollee's name and telephone number;
- The enrollee's health insurance claim number (HICN);
- The plan name;
- The ALJ appeal number;
- The specific Part D drug(s) for which the review is requested;
- A statement that the enrollee is requesting an expedited review, if applicable; and
- The enrollee's name and signature, or, if applicable, the name and signature of your representative.

Mail your appeal and a copy of the decision to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

By fax to (202) 565-0227.

By E-File on the Medicare Operations Division Electronic Filing System (MOD E-File), available at <https://dab.efile.hhs.gov/mod>. To file a new appeal using MOD E-File, you will need to register by:

- (1) Clicking **Register** on the MOD E-File home page;
- (2) Entering the information requested on the "Register New Account" form; and
- (3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at <https://dab.efile.hhs.gov/mod/users/new>. You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party's representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

- (1) Logging into MOD E-File;
- (2) Clicking the **File New Appeal** menu button on the top right of the screen;
- (3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
- (4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the "File New Appeal – Medicare Operations Division" form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed decision. All documents should be submitted in Portable Document Format (PDF) whenever possible. Any document, including a Request for Review, will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.

Currently, the documents that may be filed electronically are the:

- (1) Request for Review;
- (2) Appointment of Representative form (OMB Form 0938-0950);
- (3) Copy of ALJ decision/dismissal order;
- (4) Memorandum or brief or other written statement in support of your appeal; and
- (5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to the Administrative Law Judge for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll free phone number and mailing address are at the top of this notice.

Copies were sent to the following:

ATTN: JORGE MORALES
195 Commerce Way
Portsmouth, NH 03801

Humana Insurance Company
Humana Medical Plan, Inc.
PO Box 14165
Lexington, KY 49512-4165

Appeals Work Station
Maximus Federal Services
Medicare Part C QIC
3750 Monroe Ave., Suite 702
Pittsford, NY 14534-1302

Enclosures:

Form DAB-101, Request for Review



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, MO

Appeal of:	ALJ Appeal No.: 1-5309926775
Beneficiary:	Medicare: Part C
HICN:	Before: Kimberley Woodyard Administrative Law Judge

DECISION

Upon a *de novo* review of the record in this case, and following hearing, this Administrative Law Judge enters a **FAVORABLE** decision for . Humana Insurance Company shall pre-approve tumor treatment field therapy for

Procedural History

This appeal is before this Administrative Law Judge following prior adverse decisions of the Plan and Quality Improvement Organization, both of which denied approval of the proposed treatment. The reconsideration decision was issued on October 28, 2016, after which the Appellant filed a request for hearing before an Administrative Law Judge, on November 2, 2016.

Inasmuch as the request was timely and the amount in controversy meets the jurisdictional requirements for an ALJ hearing, 42 C.F.R. §§ 422.600, 422.602, this ALJ has jurisdiction to conduct the *de novo* review, 42 C.F.R. § 405.1000(d), and issue a decision.

Hearing on this matter was held on December 29, 2016, at which Jorge Morales, the Beneficiary's representative appeared. Humana appeared by Dr. Bruce Neibylski. Exhibits 1-4 were admitted into evidence without objection. Upon conclusion of argument and testimony, the record was closed and the hearing was concluded.

Issue

This issue is whether all plan contract coverage requirements have been met warranting payment under Title XVIII of the Social Security Act.

Findings of Fact

This Judge finds the following facts to be established by the evidence in the record:

1. [redacted] is a sixty-eight year-old man suffering from glioblastoma of the right temporal lobe. (Exh. 3, p. 3). This is a particularly aggressive malignant primary brain tumor, (Exh. 3, p. 21), with which he was diagnosed on April 8, 2015, (Exh. 3, p. 3).
2. On August 31, 2016, Dr. Dina Randazzo signed a prescription for [redacted] to receive six months of Optune -- treatment to start ASAP. (Exh. 3, p. 1).
3. [redacted] had already undergone, among other treatments, six months of radiation with concurrent temozolomide. (Exh. 3, p. 3). He continued, however, to have seizures and staring spells. (Exh. 3, p. 4). His symptoms had gotten worse since his last appointment, but were still better than several months prior, following the radiation. *Id.* [redacted] is also inflicted with diabetes and hypertension. *Id.* At his doctor visit of August 31, 2016, the heterogeneous mass in his right anterior temporal lobe that had minimally increased. *Id.* at 8. The tumor was progressive. *Id.* In light of the clinical and radiographic continued progression of the disease, Dr. Randazzo recommended that [redacted] initiate the use of Optune, and she began the paperwork for him. *Id.* The documentation of the continued progression is also supported by the physician notes of the prior encounter of August 3, 2016. (Exh. 3, pp. 11-16).
4. Optune uses low-intensity electric fields to help slow or stop glioblastoma cancer cells from dividing. See <https://www.optune.com/therapy/how-therapy-works>. Four adhesive patches, or transducer arrays, are applied to the scalp and connected to the device and a battery to deliver the therapy. *Id.*
5. Optune, previously called NovoTTF-100A System, received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011.¹
6. On October 5, 2015, the Provider received premarket approval from the FDA for use of Optune in patients newly diagnosed with glioblastoma.² The FDA approval was based upon the premarket approval process, not the abbreviated 510(k) clearance process.
7. On December 15, 2015, the Journal of the American Medical Association ("JAMA") published an article analyzing the results of a phase III clinical trial related to TTFT. Stupp, Roger, M.D. et al., *Maintenance Therapy With Tumor-Treating Field Plus Temozolomide vs Temozolomide Alone for Glioblastoma A Randomized Clinical Trial*, 314 JAMA 2535 (2015); (Exh. 3, pp. 22, et seq.). The analysis of the clinical trial showed that adding TTFT to maintenance temozolomide in a population with new onset glioblastoma "significantly prolonged progression-free and overall survival."
8. In an article published in July 2015 in Current Treatment Options in Oncology, results of a phase III clinical trial for recurrent glioblastoma were discussed, as well as interim

¹ http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100034a.pdf.

² http://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034S013a.pdf.

results in a study involving patients newly diagnosed with glioblastoma. *See* 16 Curr. Treat. Options in Oncol. 40 (2015); (Exh. 3, pp. 57 *et seq.*). This article reported that TTFT was “shown to have equivalent efficacy when compared to the best physician’s choice chemotherapy in a registration phase III clinical trial for recurrent glioblastoma.” *Id.* The results of this clinical trial then led to FDA approval for the device. *Id.* Interim results of a later clinical trial for newly diagnosed patients showed significant improvement in outcomes of the patients, leading to crossover of trial subjects from the control group to the experimental group. *Id.*

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with the decisions of the Medicare contractor and the Qualified Independent Contractor is entitled to a hearing before the Secretary of the Department of Health and Human Services, Social Security Act § 1869(b)(1)(A), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner, 42 C.F.R. § 422.602. The request for hearing is timely if filed within sixty days of the reconsideration determination. *Id.* The minimum amount in controversy required for hearing before an Administrative Law Judge are published in the Federal Register. In this instance, this ALJ uses the projected value of the services to compute the amount in controversy. 42 C.F.R. § 422.600(c).

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the Appellant’s favor. 42 C.F.R. § 405.1032(a).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue and makes a decision based on the hearing record. 42 C.F.R. § 405.1000(d).

II. Principles of Law

A. The Statutes and Regulations

Sections 1812 and 1813 of the Act establish the scope of benefits of the hospital insurance program under Medicare Part A. Section 1814 establishes conditions for, and limitations on, payment for services furnished by providers. Medicare coverage for hospitalization includes payment for the services generally available in a hospital: bed and board, nursing services and other related services, use of hospital facilities, medical social services, drugs, supplies and equipment, diagnostic or therapeutic items or services, and medical or surgical services provided by certain interns and residents pursuant to section 1861(b) of the Act. In addition, section 1861 defines hospitals to include institutions which provide “therapeutic services for medical diagnosis, treatment and care of injured, disabled, or sick persons, or rehabilitation or injured, disabled or sick persons.” Section 1862(a)(1)(A), prohibits Medicare

payments for anything which is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

In the event the services are found to be “not medically reasonable and necessary” or “custodial in nature” under section 1862(a)(1) or (a)(9) of the Act, section 1879 provides for limitation on liability for Medicare payments. If the beneficiary had no knowledge that the services would not be covered, but the provider of the services did, then the provider is liable and cannot seek or retain payment by the beneficiary. The regulations at 42 C.F.R. § 411.400 *et seq.* and HCFA Ruling 95-1 address how to determine if the beneficiary or provider/supplier had the requisite degree of knowledge to make them liable under section 1879. *See also* CMS, Medicare Claims Processing Manual (MCPM), Internet-Only Manual Pub. 100-4, Ch. 30, § 20. In general, the existence of a notice, manual, or community medical standard is sufficient to constitute notice as applicable to the provider. 42 C.F.R. § 411.406.

An MA plan must provide an enrollee with coverage for all items and services covered by Medicare Part A (except hospice services) and Part B that are available to beneficiaries in the plan's service area. *See* Section 1852 (a) (1) of the Social Security Act (Act); 42 C. F. R. §§ 422.100 (c) (1); 422.101 (a). An MA plan must comply with National Coverage Determinations (NCDs), general coverage guidelines included in original Medicare manuals and instructions, and written coverage decisions of local Medicare contractors with jurisdiction over claims in the geographic area in which services are covered under the MA plan. 42 C.F.R. § 422.101(b). Therefore, if Medicare does not cover an item or service, unless the plan covers the item or service through supplemental benefits, the Plan is not required cover the item or service at issue. *See* 42 C.F.R. § 422.102.

B. Policy and Guidance

The Social Security Act vests in the Secretary the authority to make coverage decisions. Under that authority, CMS issues National Coverage Determinations (NCDs) that state whether specific medical items, services, treatment procedures, or technologies may be paid for by Medicare. In the absence of a specific NCD, the Medicare contractor is responsible for determining whether an item or service is reasonable and necessary. (See preface to Coverage Issues Manual (reprinted at 54 Fed. Reg. 34555 (Aug. 21, 1989)). Accordingly, in addition to looking to the binding statutory and regulatory authority, this ALJ must accord substantial deference to manuals, program memoranda and other issuances issued by the Center for Medicare and Medicaid Services (CMS) and its carriers and intermediaries. 42 C.F.R. § 405.1062. Moreover, an ALJ may not set aside or review the validity of a local coverage policy in the context of a claim appeal. 42 C.F.R. § 405.1062(c). Thus, the ALJ looks to the Local Coverage Determinations (LCD), if any, and the Medicare Benefit Policy Manual.

In this instance, there is an LCD, to wit Tumor Treatment Field Therapy (TTFT)(L34823). With regard to medical necessity, it provides in full:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this local coverage determination, the criteria for “reasonable and necessary,” based

on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

For an item to be covered by Medicare, a detailed written order (DWO) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed DWO, the item will be denied as not reasonable and necessary.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

LCD 34823 (Effective July 1, 2016).³ The language in the LCD prior to this effective date is identical. LCD 34823 (effective 10/01/2015 – 7/01/2016).

Historically, in making coverage determinations, CMS has interpreted the terms "reasonable and necessary" to mean that the item or service in question is safe and effective and not experimental. CMS has further determined that the relevant tests for applying these terms are whether the item or service has been proven safe and effective based on authoritative evidence, or alternatively, whether the item or service is generally accepted in the medical community as safe and effective for the condition for which it is used. 54 Fed. Reg. 4304 (Jan. 30, 1989); 60 Fed. Reg. 48417 (Sept. 19, 1995); see also 52 Fed. Reg. 15,560 (Apr. 29, 1987). Indeed, CMS has provided guidance in the *Medicare Program Integrity Manual* (CMS Pub. 100-08) (*MPIM*) to assist contractors in developing LCDs to aid in creating relevant tests and guidance. The *MPIM* contemplates that, in making a determination as to whether an item or service is reasonable and necessary, contractors will analyze whether the item or service is safe and effective, and not experimental or investigational. *MPIM*, Ch. 13 at § 13.5.1. Contractors shall consider a service reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational; and
- Appropriate, including the duration and frequency that is considered appropriate for the service.

The *MPIM* further instructs contractors to base LCDs on the strongest evidence available at the time the determination is issued. In order of preference, this includes:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and ALJs and the Medicare Appeals Council are not bound by CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. 42 C.F.R. § 405.1062(a).

- General acceptance by the medical community (standards of practice), supported by sound medical evidence based on:

- o Scientific data or research studies published in peer-reviewed medical journals;
- o Consensus of expert medical opinion (i.e., recognized authorities in the field);

or

³ Mr. Chason made his authorization request on September 6, 2016. (Exh. 2, p. 23).

o Medical opinion derived from consultations with medical associations or other health care experts.

Id. at § 13.7.1. The Manual further explains:

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

Id.

C. The Terms of the Plan (Evidence of Coverage)

The insurance plan that governs this proceeding is located in Exhibit 1 and provides that it covers services in accord with Medicare rules. (Exh. 1, p. 53). The services “*must* be medically necessary,” which means that the services are “needed for the prevention, diagnosis, or treatment of your medical condition and meet accepted standards of medical practice.” (Exh. 1, p. 35)(emphasis in original). The plan charts what services are not covered, including, “Services considered not reasonable and necessary, according to the standards of Original Medicare.” (Exh. 1, p. 87). Another exclusion is: “Experimental medical and surgical procedures, equipment and medications. Experimental procedures and items are those items and procedures determined by our plan and Original Medicare to not be generally accepted by the medical community.” *Id.*

Analysis

seeks a decision requiring Humana Insurance Company) to pre-approve tumor treatment field therapy, asserting that the services are not experimental for his diagnosis. The Plan argued that the relevant Local Coverage Determination stated that Tumor Treatment Field Therapy was not covered by Medicare as not medically reasonable and necessary treatment. The MA Plan is bound to follow Local Coverage Determinations.

has a brain tumor that has failed other treatment and, accordingly, seeks treatment – Tumor Treatment Field Therapy. He has been through radiation and other treatment and yet his disease is progressing. Medicare, through its contractor, has issued a policy statement to which this ALJ, in the first instance, is required to accord “substantial deference.” In order to deviate from that guidance, the specific LCD applicable to this case, I must have a cogent explanation for disregarding that guidance. *See* 42 C.F.R. § 405.1062. In this instance, the grounds for disregarding the LCD are copious and warranted. The therapy has been shown to be safe and effective for use in patients with recurrent glioblastoma (after other treatments have been tried without sufficient success, all as here) and it is medically reasonable and necessary to treat Mr. Chason’s brain condition.

The relevant LCD states that tumor treatment field therapy will be denied as not reasonable and necessary. However, the Information and Basis of Decision section of the applicable version LCD showed that the most recent literature reviewed for purposes of the LCD’s formation was published in 2013. If additional or more recent literature was reviewed, it is not listed in the LCD. LCD L34823. In any event, the advancement of medicine and science

can sometimes outpace the current or relevant version of an LCD. In this case, the advancement is obvious. Indeed, subsequently reported data from the FDA, phase III clinical trials, and NCCN guidelines is available to this ALJ for review and analysis, and shows the LCD may be behind the medical literature curve as applied to this patient.

The Optune device received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011. On October 5, 2015, the FDA gave premarket approval for use of Optune in patients with newly diagnosed glioblastoma. The FDA website explains that premarket approval (“PMA”) entails the following:

PMA is the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).⁴

While FDA premarket approval does not establish that the device is medically reasonable and necessary pursuant to Medicare requirements, it does ensure that the FDA has closely examined the device and its application. In this case, the FDA determined that sufficient scientific evidence existed to provide the FDA with assurance that the device was safe and effective for its intended use both in patients with recurrent and newly diagnosed glioblastoma. From this perspective, the use of the device meets Medicare guidance requiring that a device be proven safe and effective based on authoritative evidence.

The FDA approval also helps shows that the device is safe, and not experimental or investigational Medicare does not pay for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. Social Security Act § 1862(a)(1). To be reasonable and necessary, the procedure must be safe and effective and not experimental.⁵

Second, this ALJ has reviewed clinical studies in the record related to the use of the Optune device. Results from a phase III clinical trial utilizing TTFT in patients with recurrent glioblastoma was shown to have equivalent efficacy when compared to the best physician’s choice for chemotherapy. With respect to patients newly diagnosed with glioblastoma, results of a phase III study released in a December 15, 2015, JAMA article showed that adding TTFT to maintenance temozolomide significantly prolonged progression-free and overall survival. *Id.* Significantly, patients in the control group in the JAMA-reported study crossed over to the combined therapy group for TTFT treatment due to the improvement in outcomes seen. *Id.* The results from these phase III trials also led to FDA approval for the Optune device. *Id.* Again, these trials showed that the Optune device was safe, non-investigational and effective. In

⁴<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm>.

⁵ This ALJ is mindful of the distinction between FDA approval and Medicare’s “reasonable and necessary” criteria. The FDA concentrates on the safety of a device or procedure, whereas Medicare reviews whether the procedure meets the broader requirement, “reasonable and necessary.” These entities make determinations under different statutory standards as well as different delegated authority. *See generally* 68 Fed. Reg. 55,636, 54 Fed. Reg. 4307. FDA approval does not generally entitle a procedure to coverage. 68 Fed. Reg. 55,636.

addition, these trials showed that the Optune device was appropriate for [redacted] ; individual needs, specifically the treatment of recurrent glioblastoma.

Third, the use of TTFT is generally accepted by the medical community. In the 2015 version of the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology Central Nervous System Cancers guidelines, alternating electric field therapy is a treatment option suggested for glioblastoma. This suggestion was found in a treatment guideline from a national cancer organization, not evidence based on an individual physician treating a single patient in a clinical setting. As such, this ALJ finds that TTFT treatment is generally accepted in the medical community as safe and effective for the treatment of recurrent glioblastoma.

Overall, a review of the literature available demonstrates that the Optune device received FDA premarket approval, and that it is safe and effective and not investigational/experimental. The use of the Optune device in a population with recurrent glioblastoma was proven effective and appropriate through a phase III clinical trial; and the use of the Optune device appears in national cancer treatment guidelines for treatment of glioblastoma, showing general acceptance by the medical community. A number of commercial health plans also now cover TTFT.

The final aspect is the medical record of [redacted], whose disease, without this treatment, will likely progress to cause an earlier death than need be the case. A review of the medical records and hearing demonstrated that [redacted] has already undergone extensive treatment for the cancer and there appear to be no further options; the disease is progressing despite the treatments. [redacted] has no alternative care available to halt the progression of the disease. The preponderance of the evidence is that TTFT therapy is warranted to battle the progression of disease and prolong his life.

Conclusions of Law

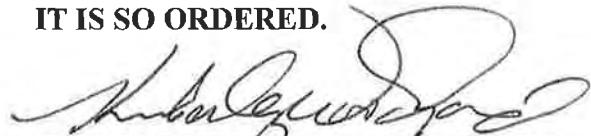
[redacted] insurance benefits are determined by the terms of his Medicare Advantage PPO plan with a Medicare contract. Under the terms of the plan, Medicare rules and coverage determinations guide whether an item or device will be covered. In order for coverage to exist, a procedure must be medically reasonable and necessary. Optune (TTFT) has been shown to be safe and effective and is medically reasonable and necessary for the treatment of Mr. [redacted] condition. Plan coverage is warranted.

Order

The Medicare Contractor is DIRECTED to process the request for pre-approval of the treatment in accord with this decision.

IT IS SO ORDERED.

Dated: JAN 9 2016



Kimberley Woodyard
U.S. Administrative Law Judge

REQUEST FOR REVIEW OF ADMINISTRATIVE LAW JUDGE (ALJ) MEDICARE DECISION / DISMISSAL

1. APPELLANT (the party requesting review)

2. ALJ APPEAL NUMBER (on the decision or dismissal)

3. BENEFICIARY*

4. HEALTH INSURANCE CLAIM NUMBER (HICN)*

*If the request involves multiple claims or multiple beneficiaries, attach a list of beneficiaries, HICNs, or other information to identify all claims being appealed.

5. PROVIDER, PRACTITIONER, OR SUPPLIER

6. SPECIFIC ITEM(S) OR SERVICE(S)

7. Medicare claim type: ☐ Part A ☐ Part B ☐ Part C - Medicare Advantage
☐ Part D - Medicare Prescription Drug Plan ☐ Entitlement/enrollment for Part A or Part B

8. Does this request involve authorization for an item or service that has not yet been furnished?

☐ Yes If Yes, skip to Block 8.
☐ No If No, Specific Dates of Service:

9. If the request involves authorization for a prescription drug under Medicare Part D, would application of the standard appellate timeframe seriously jeopardize the beneficiary's life, health, or ability to regain maximum function (as documented by a physician) such that expedited review is appropriate? ☐ Yes ☐ No

I request that the Medicare Appeals Council review the ALJ's ☐ decision or ☐ dismissal order [check one] dated _____. I disagree with the ALJ's action because (specify the parts of the ALJ's decision or dismissal you disagree with and why you think the ALJ was wrong):

(Attach additional sheets if you need more space)

PLEASE ATTACH A COPY OF THE ALJ DECISION OR DISMISSAL ORDER YOU ARE APPEALING.

DATE			DATE		
APPELLANT'S SIGNATURE (the party requesting review)			REPRESENTATIVE'S SIGNATURE (include signed appointment if not already submitted.)		
PRINT NAME			PRINT NAME		
ADDRESS			ADDRESS		
CITY, STATE, ZIP CODE			CITY, STATE, ZIP CODE		
TELEPHONE NUMBER	FAX NUMBER	E-MAIL	TELEPHONE NUMBER	FAX NUMBER	E-MAIL

(SEE FURTHER INSTRUCTIONS ON PAGE 2)

If you have additional evidence, submit it with this request for review. If you need more time, you must request an extension of time in writing now, explaining why you are unable to submit the evidence or legal argument now.

If you are a provider, supplier, or a beneficiary represented by a provider or supplier, and your case was reconsidered by a Qualified Independent Contractor (QIC), the Medicare Appeals Council will not consider new evidence related to issues the QIC has already considered unless you show that you have a good reason for submitting it for the first time to the Medicare Appeals Council.

IMPORTANT: Include the HICN and ALJ Appeal Number on any letter or other material you submit.

This request must be received within 60 calendar days after you receive the ALJ's decision or dismissal, unless we extend the time limit for good cause. We assume you received the decision or dismissal 5 calendar days after it was issued, unless you show you received it later. If this request will not be received within 65 calendar days from the date on the decision or dismissal order, please explain why on a separate sheet.

You must file your request for review in writing with the Medicare Appeals Council at:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

You may send the request for review by U.S. Mail, a common carrier such as FedEx, or by fax to (202) 565-0227. If you send a fax, please do not also mail a copy. **You must send a copy of your appeal to the other parties and indicate that all parties, to include all beneficiaries, have been copied on the request for review. For claims involving multiple beneficiaries, you may submit a copy of the cover letters issued or a spreadsheet of the beneficiaries and addresses who received a copy of the request for review.**

If you have any questions about your request for review or wish to request expedited review of a claim involving authorization of your prescription drug under Medicare Part D, you may call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100. You may also visit our web site at www.hhs.gov/dab for additional information on how to file your request for review.

PRIVACY ACT STATEMENT

The collection of information on this form is authorized by the Social Security Act (section 205(a) of title II, section 702 of title VII, section 1155 of Title XI, and sections 1852(g)(5), 1869(b)(1), 1871, 1872, and 1876(c)(5)(B) of title XVIII, as appropriate). The information provided will be used to further document your claim. Information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your claim. Information you furnish on this form may be disclosed by the Department of Health and Human Services or the Social Security Administration to another person or governmental agency only with respect to programs under the Social Security Act and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services, the Social Security Administration, or other agencies.



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, MO

Appeal of:	ALJ Appeal No.: 1-5309926775
Beneficiary:	Medicare: Part C
HICN:	Before: Kimberley Woodyard Administrative Law Judge

EXHIBIT LIST

EXHIBIT NUMBER	DESCRIPTION	PAGE NUMBERS
1	Evidence of Coverage	1-223
2	Organization Determination, MAO Reconsideration and Part C QIC Reconsidered Decision Procedural Documents	1-53
3	Medical Records/Evidence received by MAO and CMS contractors	1-105
4	Request for ALJ Hearing	1-4
5	OMHA Proceedings	1-22
6	Post-Hearing submission – Legal materials (not evidence)	1-87

Dated: January 7, 2017



**Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND
APPEALS**

**Arlington Field Office
Arlington, Virginia**

Appellant:

ALJ Appeal No.: **1-7708321227**

Enrollee:

Medicare Part: **C**

HICN: *******6196A**

Before: **James Myles
U.S. Admin. Law Judge**

DECISION

After carefully considering the evidence in the record and arguments presented in the hearing, a **FAVORABLE** decision is entered for (Appellant/Enrollee).

PROCEDURAL HISTORY

Appellant is enrolled in the Cariten Health Plan, Inc., a Medicare Advantage Plan administered by Humana (hereinafter "Humana" or the "Plan"). Appellant submitted a claim to the Plan for pre-approval of an electrical stimulation device used for cancer treatment (HCPCS E0766) to be provided by the Provider, Novocure, Inc. (also known as Optune). On May 27, 2018, Humana's Medical Doctor denied the request because the information submitted failed to meet medical necessity criteria of Local Coverage Determination (LCD) L34823 for Tumor Treatment Field Therapy ("TTFT"). (Exh. 1 at 6).

Appellant requested reconsideration from Maximus Federal Services (MAXIMUS), a Medicare Qualified Contractor (the "QIC"). In an unfavorable decision dated May 18, 2018 the QIC denied coverage on the basis that the medical records did not meet the requirements of Local Coverage Determination (LCD) L34823. (Exh. 2 at 3).

Appellant timely requested a hearing before an Administrative Law Judge to review MAXIMUS' denial of Medicare Part C benefits. (Exh. 3). The amount in controversy meets the jurisdictional amount; therefore, there is jurisdiction to hear this case.

An Administrative Law Judge ("ALJ") hearing was conducted by telephone conference before ALJ James Myles on August 28, 2018. At the hearing, the beneficiary's interest was represented by Novocure, the Provider, which was in turn represented by Stephen Hales, Esq. Also appearing for the Provider were Dan McCoy, and Julie Miles (Clinical Specialist). Humana was notified of the hearing date and time in writing with adequate notice. Humana did not respond to the notice of hearing. Prior to the hearing, Humana was contacted by OMHA regarding the hearing both by telephone and e-mail, but still did not appear at the hearing. The telephone hearing was conducted without Humana and the record was left open in the event Humana could demonstrate good cause for failure to appear and wished to have a supplemental hearing. After the hearing held on August 28, 2018 an Order to Show Cause for failure to appear was mailed to Humana. Humana did not respond to the Show Cause within 10 days as required. The record is now closed. Exhibits 1-5 were admitted in the record.

ISSUE

Whether Cariten Health Plan, Inc. (Humana) is required to cover an electrical stimulation device used for cancer treatment (HCPCS E0766) provided by the Appellant/Provider Novocure, Inc. to the Enrollee/Beneficiary?

FINDINGS OF FACT

1. The beneficiary is a 72 year-old male who has the unfortunate diagnosis of glioblastoma. (Exh. 2 at 7). The beneficiary had his mass, which was located in the right parietal lobe, reduced in October of 2016. (*Id.*)
2. The beneficiary's physician recommends continued TTFT to manage his glioblastoma. (*Id.*)
3. The Plan denied coverage based on LCD L34823, released in October 2015, which LCD states that TTFT (E0766) will be denied as not reasonable and necessary. (Exh. 1 at 3).
4. Humana released an updated Medicare Coverage Policy on February 22, 2018. (Exh. 5). This policy states that TTFT will be covered in circumstances where:

Absence of any contraindication listed in the Coverage Limitations section; AND

22 years of age or older; AND

Combined ETTF and temozolomide in individuals with histologically-confirmed newly diagnosed GBM limited to the supratentorial region following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy; OR

Monotherapy for individuals diagnosed with histologically- or radiologically - confirmed recurrent GBM limited to the supratentorial region following treatment with chemotherapy after surgical and radiation treatments have been exhausted.

The contraindications states in the new Humana Medicare Policy include:

- Active implanted medical device (eg, deep brain stimulators, spinal cord stimulators, pacemakers, defibrillators); OR
- Bullet fragments; OR
- Pregnancy; OR
- Shunts; OR
- Skull defects (eg, missing bone with no replacement); OR
- Treatment of other malignant tumors (eg, breast, lung, pancreas)

LEGAL FRAMEWORK

A. Jurisdiction

An individual or organization that is dissatisfied with a reconsideration of a Contractor's initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services ("Secretary") provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act § 1869(b)(1)(A). The Secretary administers the nationwide hearings and appeals system through the Office of Medicare Hearings and Appeals ("OMHA"). Administrative Law Judges ("ALJs") within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council.

A request for hearing meets the amount in controversy requirement if it comports with 42 C.F.R. § 405.1006(b)(1). A request for hearing is timely if filed within sixty days after receipt of the notice of the Qualified Independent Contractor decision. 42 C.F.R. § 405.1002(a)(1).

B. Scope of Review

"The issues before the administrative law judge include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in [the appellant's] favor. However, if evidence presented before or during the hearing causes the administrative law judge to question a fully favorable determination, he or she will notify [the appellant] and will consider it an issue at the hearing." 42 C.F.R. § 405.1032(a).

The ALJ may decide a case on the record and not conduct an oral hearing if the decision is fully favorable, or if the appellant indicates in writing that he does not wish to appear before the ALJ at a hearing. 42 C.F.R. § 405.1038.

C. Standard of Review

“The ALJ conducts a de novo review and issues a decision based on the hearing record.” 42 C.F.R. § 405.1000(d).

Principles of Law

A. Statutes and Regulations

According to § 1862(a)(1)(A) of the Social Security Act (“Act”), Medicare may not make a payment under part A or part B for anything which is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

B. Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than an NCD, can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. (*See also* 42 C.F.R. § 405.860). However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that establishes criteria for coverage of selected types of medical items and services in the form of manuals and local coverage determinations (LCDs). Administrative Law Judges are not bound by LCDs, but will give substantial deference to these policies when applicable. (42 C.F.R. § 405.1062). If an Administrative Law Judge does not follow a policy in a particular case, the Administrative Law Judge must explain why in the decision. (42 C.F.R. § 405.1062).

CMS Medicare Managed Care Manual (MMCM), 100-16, Ch. 40 sets forth specific guidance regarding Medicare cost plans.

Although not subject to the force and effect of law, CMS and its contractors issue policies, manuals and guidelines that describe criteria for coverage of selected types of medical items and services in the form of manuals and local coverage determinations (LCDs). 42 C.F.R. § 405.1062 states that an ALJ is not bound by LCDs or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. If an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed. An ALJ decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.

LCD L34823 entitled "Tumor Treatment Field Therapy (TTFT)" provides that TTFT (E0766) will be denied as not reasonable and necessary.

The undersigned notes that the LCD contains a blanket citation to authorities for support but provides no rationale, discussion or criteria upon which exceptions can be made within the context of the LCD, or upon which the LCD is based. Moreover, it does not discuss what authorities it specifically relies upon, nor what the authorities purport to state.

Policy Article A52711 provides additional guidance for TIFT, and seems to provide some inconsistent analysis with the LCD, as follows:

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed- body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary"). Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Code E0766 is in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories. Separate billing of supplies and/or accessories will be denied as unbundling.

The accompanying Policy Article establishes that TTFT is categorized under the Durable Medical Equipment benefit. The article explains that code E0766 describes "devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers." The article further states that TTFT devices are in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories. While it defers to any applicable LCD it seems to confirm categorically that in particular cases such treatments should be found to be medically reasonable and necessary. Additionally, it anticipates that any applicable LCD will provide eligibility criteria.

C. Evidence of Coverage

The Plan at issue is a Medicare Advantage Plan. The Plan's EOC states that as a Medicare health plan, the plan "must cover all services covered by Original Medicare and must follow Original Medicare's coverage rules." (Exh. 1 at 87). Covered services include "all the medical care, health care services, supplies, and equipment that are covered by our plan." (*Id.*)

ANALYSIS

After careful consideration of the evidence and arguments presented, the undersigned ALJ finds that the Novocure/Optune treatment is reasonable and necessary for purposes of coverage under Medicare Part C for the Enrollee/Beneficiary.

An MA plan must provide an enrollee with coverage for all items and services covered by Medicare Part A (except hospice services) and Part B that are available to beneficiaries in the plan's service area. See Section 1852 (a) (1) of the Social Security Act (Act); 42 C.F.R. §§422.100. An MA plan must comply with National Coverage Determinations (NCDs), general coverage guidelines included in original Medicare manuals and instructions, and written coverage decisions of local Medicare contractors with jurisdiction over claims in the geographic area in which services are covered under the MA plan. Therefore, if Medicare does not cover an item or service, unless the plan covers the item or service through supplemental benefits, the Plan is not required to cover the item or service at issue. See 42 C.F.R. § 422.102.

An LCD is program guidance developed by a Medicare contractor and is applicable only in that contractor's service area. An ALJ is not bound by program guidance such as LCDs, program memoranda, or manual instructions. However, an ALJ must give such policies substantial deference if applicable in a particular case. 42 C.F.R. § 405.1062(a). If an ALJ declines to follow a policy in a particular case, the rationale for not following that policy must be explained. 42 C.F.R. § 405.1062(b).

At the hearing Mr. Hales discussed that the beneficiary's claim for coverage was denied by Humana and the Part C QIC based on Humana's reliance on the LCD. (Hearing Record). Mr. Hales argued that TTFT treatment should be available for [redacted] because a departure from the LDC is appropriate here. (*Id.*) Mr. Hales argued that the plan was required to follow the LCD, but noted that the ALJ has the discretion to decline to follow the policy put forth in an LCD. (*Id.*) Mr. Hales stated that Humana does provide coverage for TTFT to its non-Medicare members now and noted that the FDA has approved TTFT treatment for patients with initial glioblastoma diagnoses since the LCD became active. (*Id.*) Ms. Hales then gave an overview of the present case. (*Id.*) Mr. Hales testified that the NCCN is the recommended compendia for providers of cancer treatments and noted the favorable treatment of TTFT in the NCCN and multiple published articles and journals. (*Id.*) Mr. Hales also noted the recent development of the LCD which the contractor accepted August 7, 2018. (*Id.*)

Ms. Miles testified regarding the beneficiary's symptoms and diagnosis which was glioblastoma, a very aggressive and rare form of brain cancer. (*Id.*) Ms. Miles testified that the beneficiary had radiation treatment to reduce his tumor size in December of 2016 and noted that in February of 2017 the beneficiary began TTFT. (*Id.*) Ms. Miles noted that the beneficiary is doing well clinically and stated that the most recent MRI they had for him, which was dated February 20, 2018, showed no significant changes in tumor size. (*Id.*) Ms. Miles discussed the recent acceptance by the FDA of TTFT treatment for newly diagnosed and reoccurrences of glioblastoma. (*Id.*) Ms. Miles also discussed recent studies and positive trials and noted that one study was even aborted mid-stream when it was discovered that the TTFT was so effective, it

was determined to be unfair to continue to deny the treatment to the patients in the placebo group. (*Id.*) Ms. Miles concluded by testifying regarding the benefits of TTFT and how it has impacted the glioblastoma universe through statistically significant improvement in survival rates. (*Id.*)

As mentioned above, the Provider argues that many ALJs have approved coverage of TTFT. The Provider also argues that the applicable LCD and accompanying Policy Article include only citations to outdated clinical studies and do not incorporate more successful clinical trials and studies showing the success of the TTFT treatment. The fact that many insurance companies and ALJs have approved coverage does not affect the independent judgment of the undersigned ALJ since neither insurance companies nor other ALJs decisions to coverage the TTFT treatment have precedential effect, although those determinations are noted and considered here. The undersigned ALJ does find the Provider's argument regarding updated peer review articles and clinical trials/studies to be persuasive. The Provider has pointed out that the FDA and NCCN have recently approved use of TTFT for initially diagnosed glioblastoma patients such as Mr. Stephenson. Furthermore, Humana's own internal policy dated February 22, 2018 essentially overrides the LCD with respect to coverage of this treatment being provided to Medicare Advantage Plan enrollees like Mr. Stephenson. And, Humana's non-Medicare enrollees have been covered for TTFT treatment for a while.

Pursuant to 42 C.F.R. § 405.1062, Medicare regulations permit an ALJ to decline to follow a local coverage policy in individual cases if he/she sets forth specific reasons. After carefully weighing all of the factors in this case, the undersigned ALJ declines follow the applicable LCD L34823 in this particular case.

The undersigned ALJ agrees with the Provider's contention that the citations and authorities relied upon in LCD L34823 are outdated and do not necessarily reflect the current consensus of the medical community. Indeed, Humana's own internal Medicare policy, evidently overlooked by the employees who were reviewing this particular appeal, has changed to accept TTFT as an appropriate treatment which should be covered when certain patient criteria are met – and those criteria are met by n. The evidence in the record indicates that the TTFT treatment has increased s life span and is more likely than not going to continue to increase his life span survival by several months or more.

As discussed above, the applicable LCD L34823 does not consider or address recent breakthrough results or generally accepted consensus from the medical community. For these reasons, the undersigned ALJ declines to follow the applicable LCD in this case.

The undersigned ALJ finds that the TTFT device known as Optune is medically reasonable and necessary for the Enrollee/Beneficiary. Humana must provide coverage for the TTFT at issue. The medical record contains sufficient documentation of the Enrollee/Beneficiary's medical diagnosis of malignant neoplasm of the brain to substantiate the medical reasonableness and necessity for the Optune treatment at issue, satisfying Medicare rules and regulations.

CONCLUSION OF LAW

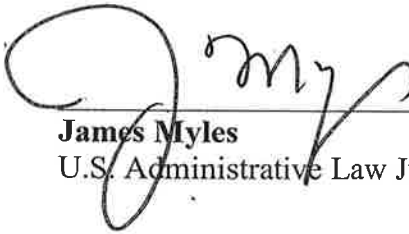
In accordance with the Plan's EOC and the Plan's February 22, 2018 internal policy update, and based on the ALJs reasoning with regard to departure from the applicable LCD, the Plan is required to pre-approve Tumor Treatment Field Therapy for Appellant/Enrollee.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated: SEP 13 2018


James Myles
U.S. Administrative Law Judge



Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

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1614433

August 2, 2017

NOVOCURE
ATTN: SYED ALI
195 COMMERCE WAY
PORTSMOUTH, NH 03801

NOTICE OF DECISION

Appellant: 

OMHA Appeal Number: 1-6210417199

Enclosed is the decision for the above case. This decision is based on the administrative record, including any evidence or testimony presented at the hearing, if one was held. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault. In addition, the decision may be reopened within 180 days of the decision for good cause. Good cause exists when there is new and material evidence that was not available or known at the time of the decision and may result in a different conclusion, or when the evidence that was considered clearly shows on its face that an obvious error was made at the time of the decision.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. Other parties may also appeal the decision. In addition, the Medicare Appeals Council may decide to review the decision on its own motion. If no party appeals the decision and the Medicare Appeals Council does not review the decision, the decision is binding on all parties and you and the other parties will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.

How much time do I have to file an appeal?

The Medicare Appeals Council must receive your written appeal **within 60 calendar days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 calendar days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing, except that a request for expedited review of a Part D decision may be made orally as described below. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree.

You may submit a written request for review to the Medicare Appeals Council using one of three available methods: mail, fax, or electronic filing (E-File). **Please do not submit your request for review using more than one method.** Regardless of how you file your appeal, **you must always send a copy of your written request for review to the other parties who received a copy of the decision.**

If you are filing a written request for review, you may use the enclosed *Request for Review* (Form DAB-101), or you may write a letter containing the following:

- The beneficiary's/enrollee's name (and telephone number for Part D appeals);
- The beneficiary's/enrollee's health insurance claim number;
- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's dismissal;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's decision (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

Filing by mail:

Mail your appeal and a copy of the enclosed decision to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Filing by fax:

Fax your appeal and a copy of the enclosed dismissal to (202) 565-0227.

Filing by computer:

Using your web browser, visit the Medicare Operations Division Electronic Filing System (MOD E-File) website at <https://dab.efile.hhs.gov/mod>.

To file a new appeal using MOD E-File, you will need to register by:

- (1) Clicking **Register** on the MOD E-File home page;
- (2) Entering the information requested on the "Register New Account" form; and
- (3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at <https://dab.efile.hhs.gov/mod/users/new>. You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party's representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

- (1) Logging into MOD E-File;
- (2) Clicking the **File New Appeal** menu button on the top right of the screen;
- (3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
- (4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the "File New Appeal – Medicare Operations Division" form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed decision. All documents should be submitted in Portable Document Format (PDF) ~~whenever possible. Any document, including a Request for Review,~~ will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.

Currently, the documents that may be filed electronically are the:

- (1) Request for Review;
- (2) Appointment of Representative form (OMB Form 0938-0950);
- (3) Copy of Administrative Law Judge or attorney adjudicator decision;
- (4) Memorandum or brief or other written statement in support of your appeal; and
- (5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D decision may be made by telephone to (866) 365-8204. You must provide the information listed in the bullet points above and a statement that

you are requesting an expedited review. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file. Please note that your request for review will only be expedited if the Part D drug has not already been furnished and the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at <http://www.hhs.gov/dab/>. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll free) if you have questions about filing an appeal.

cc:

HUMANA INSURANCE COMPANY
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Louisville, KY 40202
FAX: 502-508-8182

Maximus Federal Services
QIC Part C Appeals – ALJ
3750 Monroe Ave, Suite 702
Pittsford, NY 14534-1302

PO BOX 4151
CLARKSBURG, WV 26302-4151

Enclosures:

OMHA-156, Exhibit List
OMHA-152, Decision
DAB-101, Request for Review



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, Missouri

Appeal of: _____	ALJ Appeal No.: 1-6210417199
Enrollee: _____	Medicare Part C
HICN: *****9958A	Before: Aaron R. Raff U.S. Administrative Law Judge
MA Plan: Humana	

DECISION

After careful consideration of all the evidence and arguments presented in the hearing and record, this Administrative Law Judge ("ALJ") enters a **FULLY FAVORABLE** decision for the Enrollee, _____ ("Enrollee").

Procedural History

The Enrollee requested pre-approval for Tumor Treatment Field Therapy (TTFT) (E0766). Humana, (the "Plan") denied coverage initially and on redetermination. The decision was appealed and on April 3, 2017, MAXIMUS Federal Services held that the Plan was not required to cover the TTFT. (Exh. 1, pp. 3-4).

On May 4, 2017, the Office of Medicare Hearings and Appeals ("OMHA") received the Appellant's timely request for an ALJ Hearing. 42 C.F.R. 422.600 and .602 (Part C) referring to 42 C.F.R. § 405.1014. On July 27, 2017, this ALJ held a hearing by telephone. The Enrollee appeared by his representative Sean Mcgartland of Novocare. The Plan appeared by Cynthia McCloud and Dr. Martha Willoughey, M.D. The parties were advised of their right to counsel and knowingly and intelligently waived the same. This ALJ carefully considered the hearing testimony, argument and record. All exhibits were admitted into the record without objection, and the parties testified under oath.

Issues

The issues before the Administrative Law Judge include all of the issues brought out in the initial determination, coverage determination, or organization determination; redetermination; or reconsideration that were not decided entirely in a party's favor, for the claims or other appealed matters specified in the request for hearing.

Findings of Fact

After careful consideration of the entire record (Exhibit List attached and incorporated herein), a preponderance of the evidence establishes the following facts:

1. The Medicare Part C Independent Review Entity ("IRE") determined that Humana did not have to pre-approve the requested device or treatment. (Exh. 1, pp. 3-4). In reaching this decision the IRE relied on local coverage determination L34823 which stated that tumor treatment field therapy and related devices will be denied as not reasonable and necessary. *Id.*
2. The Enrollee became active with Humana on January 1, 2013. (Exh. 3, p. 7).
3. The Enrollee is a 70 year old male. (Exh. 2, p. 4; Hearing testimony). On March 9, 2016, the Enrollee presented to his physician with complaints of headache, disorientation, and gait imbalances. *Id.* An MRI revealed a 4.5 x 3.3 x 3.6 cm T1 and T2 heterogeneous medical right temporal lobe mass lesion with hemorrhage. *Id.*
4. On March 11, 2016, the Enrollee underwent a right frontal craniotomy and tumor resection. (Exh. 2, pp. 4, 15-17, 21). Resultant pathology was consistent with glioblastoma. *Id.*
5. Glioblastoma is an aggressive, malignant, primary brain tumor. (Exh. 1, p. 14). Prognosis for glioblastoma is poor and has a median survival time of approximately 14 months, despite multiple available treatments including craniotomy with surgical resection, chemotherapy, radiotherapy antiangiogenic, and symptomatic management.
6. The Enrollee completed Temodar on April 7, 2016. (Exh. 2, p. 4).
7. Physician notes dated February 3, 2017, indicated that the Beneficiary's last MRI showed recurrence and swelling. (Exh. 2, pp. 4-8, 26). In sum, prior to the TTFT at issue, the Enrollee tried a mixture of radiation, chemotherapy and surgery treatments without sufficient success. The glioblastoma had reoccurred. (Exh. 2).
8. On February 3, 2017, the Enrollee was prescribed Optune for a six month period. (Exh. 2, p. 2; Hearing testimony).

9. Optune uses low-intensity electric fields to help slow or stop glioblastoma cancer cells from dividing. (Exh. 3, p. 271). Four adhesive patches, or transducer arrays, are applied to the scalp and connected to the device and a battery to deliver the therapy. *Id.*
10. Optune, previously called NovoTTF-100A System, received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011.¹ (Exh. 1, p. 11; Exh. 2, pp. 114-118; Hearing testimony). The device was indicated for treatment of adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme, following histologically-or radiologically confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. *Id.*
11. In 2015, the National Comprehensive Cancer Network guidelines were updated to include TTFields treatment for recurrent glioblastoma. (Exh. 1, p. 13; Hearing testimony).
12. In an article published in July 2015 in Current Treatment Options in Oncology, results of a phase III clinical trial for recurrent glioblastoma were discussed, as well as interim results in a study involving patients newly diagnosed with glioblastoma. *See* 16 Curr. Treat. Options in Oncol. 40 (2015); (Exh. 2, pp. 101-110). This article reported that TTFT was “shown to have equivalent efficacy when compared to the best physician’s choice chemotherapy in a registration phase III clinical trial for recurrent glioblastoma.” *Id.* The results of this clinical trial then led to FDA approval for the device. *Id.* Interim results of a later clinical trial for newly diagnosed patients showed significant improvement in outcomes of the patients, leading to crossover of trial subjects from the control group to the experimental group. *Id.*
13. On December 15, 2015, the Journal of the American Medical Association (“JAMA”) published an article analyzing the results of a phase III clinical trial related to TTFT.² (Exh. 3, pp. 369-379). The analysis of the clinical trial showed that adding TTFT to maintenance temozolomide in a population with new onset glioblastoma “significantly prolonged progression-free and overall survival.” *Id.* After conclusion of the study, patients in the control group with ongoing maintenance therapy were offered TTFT therapy. *Id.* Thirty-five of those patients chose to receive TTFT therapy. *Id.*
14. The National Comprehensive Cancer Network (“NCCN”) included alternating electric field therapy for glioblastoma in its NCCN Clinical Practice Guidelines in oncology Central Nervous System Cancers guidelines version 1.2015. (Exh. 3, pp. 365-368).
15. At hearing, the Appellant explained the Enrollee’s medical history and progression of the glioblastoma. (Hearing testimony). After multiple rounds of treatment, disease progression was found. *Id.* The Enrollee began using the Optune device on February 27, 2017. *Id.* The Optune device received FDA approval in April 2011 for use with recurrent glioblastoma and exhibits minimal toxicity and provides patients with a better

¹ http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100034a.pdf.

² Stupp, Roger, M.D. et al., *Maintenance Therapy With Tumor-Treating Field Plus Temozolomide vs Temozolomide Alone for Glioblastoma A Randomized Clinical Trial*, 314 JAMA 2535 (2015); (Exh. 3, pp. 369-379).

quality of life than other treatments. *Id.* Further, the NCCN guidelines were updated in 2015 to include alternating electric field therapy for treatment of glioblastoma. *Id.* The Appellant further argued that if the Enrollee had a commercial plan he may have received coverage. *Id.*

16. The listed support for the LCD is based on literature from 2013 and earlier. (Hearing testimony).
17. The Plan argued that the relevant Local Coverage Determination stated that Tumor Treatment Field Therapy was not covered by Medicare as not medically reasonable and necessary treatment. (Hearing testimony).

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

A party that is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services, provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. 42 C.F.R. 422.600 and .602 (Part C) referring to 42 C.F.R. § 405.1014; Social Security Act (“the Act”) section 1869(b)(1)(A). The Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, unless later reviewed by the Medicare Appeals Council. *Id.*

To be considered timely, the request for hearing must be received by OMHA within sixty days after the Appellant receives the QIC’s reconsideration decision. The Appellant is presumed to have received the QIC’s reconsideration five days after the date noted on the first page of the reconsideration, unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3).

B. Scope of Review

The ALJ considers all issues not decided entirely in the Appellant’s favor at any prior level of review. 42 C.F.R. § 405.1032. This ALJ may give notice to the parties if any other issue will be addressed at the hearing. *Id.* This ALJ may also issue a decision on the record on his or her own initiative if the evidence in the hearing record supports a fully favorable finding. 42 C.F.R. §§ 405.1000(g), 405.1038(a).

C. Standard of Review

The ALJ reviews and evaluates the evidence without regard to the findings made by the lower levels on the claim (*de novo* review). 42 C.F.R. § 405.1000(d). The Appellant bears the burden of proving each element of the Medicare claim. Act §§ 1814(a)(1), 1815(b), 1833(e); 42 C.F.R. §§ 424.5(a)(6), 405.1018, 405.1028, 405.1030.

II. Principles of Law

A. Statutes & Regulations

The Medicare Advantage (“MA”) program (Part C) provides that a MA organization offering a MA plan must provide enrollees, at a minimum, with all basic Medicare-covered services by furnishing the benefits directly or through arrangements, or by paying for the benefits. Basic benefits are benefits defined as “all Medicare covered services, except hospice services.” Mandatory supplemental benefits are defined as “services not covered by Medicare that an MA enrollee must purchase as part of an MA plan that are paid for in full, directly by (or on behalf of) Medicare enrollees, in the form of premiums or cost sharing. Optional supplemental benefits are defined as “health services not covered by Medicare that are purchased at the option of the MA enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost sharing. These services may be grouped or offered individually.” Act §1852(a); 42 CFR § 422.100.

An MA organization’s health plan must provide coverage for all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B). Further, MA organizations must comply with national coverage determinations as promulgated by the Centers for Medicare and Medicaid Services, general coverage guidelines included in original Medicare manuals and instructions, and written coverage decisions of local Medicare contractors with jurisdiction. 42 CFR § 422.101.

Notwithstanding any other provision of Title XVIII, “no payment may be made under part A or part B for any expenses incurred for items or services-which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” Act § 1862(a)(1). Custodial care expenses are also excluded from Medicare Coverage. Act § 1862(a)(9); 42 C.F.R. § 411.15(g), (k).

B. Policy and Guidance

ALJ’s must give the manuals and rulings substantial deference. 42 C.F.R. § 405.1062(a). Unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than a National Coverage Determination (“NCD”), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. Act § 1871(a)(2); 42 C.F.R. § 405.1060. However, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local coverage determinations (“LCDs”). The applicable provisions in the LCDs and Medicare manuals are entitled to substantial deference to the extent they are consistent with the Act, regulations, and rulings; deviation from them must be explained. 42 C.F.R. § 405.1062. All relevant LCDs and Medicare manuals are hereby given substantial deference. 42 C.F.R. § 406.1060.

MA organizations must comply with national coverage determinations as promulgated by the Centers for Medicare and Medicaid Services, in addition to general coverage guidelines included

in original Medicare manuals and instructions, and written coverage decisions of local Medicare contractors with jurisdiction. 42 C.F.R. § 422.101.

A CGS Administrators LLC, Local Coverage Determination, LCD L34823, Tumor Treatment Field Therapy is relevant for this case. This LCD provides that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. CGS Administrators, LLC, Local Coverage Determination L34823: Tumor Treatment Field Therapy (LCD L34823) (Jan. 2017). The related Policy Article states that tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit and must meet the reasonable and necessary requirements set out in the related LCD to be eligible for reimbursement. CGS Administrators, LLC, Local Coverage Article for Tumor Treatment Field Therapy Article A52711 (Article A52711) (Jan. 2017).

The Medicare Program Integrity Manual (CMS Pub. 100-08) (MPIM), ch. 13 § 13.5.1, and the Medicare Benefit Policy Manual (CMS Pub. 100-02) (MBPM), ch. 15 § 110, provide guidance for determining whether a device is reasonable and necessary. These manuals suggest that a device is not reasonable and necessary if it is:

- Not “safe” and “effective” – that is, if the device has not been “proven safe and effective based on authoritative evidence” or is not “generally accepted in the medical community as safe and effective for the condition for which it is used.”
- “Experimental” – that is, “investigational”;
- Not “[a]ppropriate” for the individual beneficiary’s needs; or
- “[S]ubstantially more costly than a medically appropriate and realistically feasible alternative pattern of care.”

See also *Almy v. Sebelius*, 679 F.3d 297, 299 (4th Cir. 2012).

The claimant has the burden to show that the device is reasonable and necessary. *Almy*, 679 F.3d at 305.

Medicare also instructs contractors as to the type of evidence to be used in making these technical determinations. Such decisions should be based on either “published authoritative evidence” such as “definitive randomized clinical trials” or “general acceptance by the medical community,” with the caveat that “[a]cceptance by individual health care providers” and “limited case studies distributed by sponsors with a financial interest in the outcome[] are not sufficient evidence of general acceptance by the medical community.” MPIM § 13.7.1; see also *Almy*, 679 F.3d at 300.

C. Medicare Advantage (“MA”) Plan

Humana’s Evidence of Coverage details the services covered by the MA Plan. (Exh. 3). The Plan covers all services covered by Original Medicare and must follow Original Medicare’s coverage rules. (Exh. 3, p. 60). Medically necessary is defined in the MA Plan Evidence of Coverage as “services, supplies, or drugs [which] are needed for the prevention, diagnosis, or treatment of your medical condition and meet accepted standards of medical practice.” *Id.*

Analysis

This Administrative Law Judge conducted a *de novo* review of the evidence to determine whether the Appellant established the requirements for Medicare coverage. Appellant's request for an ALJ hearing was timely and satisfied jurisdictional requirements. In this case, this ALJ finds and concludes that the tumor treatment field therapy for treatment of this Enrollee's glioblastoma for the dates of service was medically reasonable and necessary.

Medicare Advantage plans must pay for a medical service if original Medicare would cover it. 42 C.F.R. § 422.101. The Plan may also offer additional benefits to those covered by original Medicare if it so chooses. 42 C.F.R. § 422.102. The Plan in this case covers all services provided by original Medicare. (Exh. 4, p. 44).

First, this ALJ notes that there is no National Coverage Determination specific to tumor treatment field therapy. This ALJ, therefore, looks to the relevant LCD for guidance. ALJs are not bound by LCDs and will give substantial deference to the policies if they are applicable to a particular case. 42 C.F.R. § 405.1062. If an ALJ declines to follow an LCD in a particular case, the ALJ must explain the reasons why the policy was not followed. *Id.*

In this case, this ALJ declines to follow LCD L34823 for multiple reasons as further discussed. In general, this ALJ finds that the therapy has been shown to be safe and effective for use in patients with recurrent glioblastoma (after chemotherapy, radiation and/or surgery has been tried without sufficient success, all as here with this Enrollee) and it is medically reasonable and necessary to treat the Enrollee's condition.

The relevant LCD states that tumor treatment field therapy will be denied as not reasonable and necessary. However, this ALJ notes that the Information and Basis of Decision section of the applicable version LCD showed that the most recent literature reviewed for purposes of the LCD's formation was published in 2013. If additional or more recent literature was reviewed, it is not listed in the LCD. LCD L34823.

In any event, the advancement of medicine and science can sometimes outpace the current or relevant version of an LCD. Subsequently reported data from the FDA, phase III clinical trials and NCCN guidelines is available to this ALJ for review and analysis, and shows the LCD may be behind the medical literature curve as applied to this patient. The ALJ now reasons through the evidence in the record and the parties' contentions in more detail below.

First, this ALJ finds that the Optune device received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011. On October 5, 2015, the FDA gave premarket approval for use of Optune in patients with newly diagnosed glioblastoma. The FDA website explains that premarket approval ("PMA") entails the following:

PMA is the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the

PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).³

While FDA premarket approval does not establish that the device is medically reasonable and necessary pursuant to Medicare requirements, it does ensure that the FDA has closely examined the device and its application. In this case, the FDA determined that sufficient scientific evidence existed to provide the FDA with assurance that the device was safe and effective for its intended use both in patients with recurrent and newly diagnosed glioblastoma. From this perspective, the use of the device meets Medicare guidance requiring that a device be proven safe and effective based on authoritative evidence.

The FDA approval, along with the other evidence below, also helps shows that the device is safe, and not experimental or investigational Medicare does not pay for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. Act § 1862(a)(1). To be reasonable and necessary, the procedure must be safe and effective and not experimental.

Second, this ALJ has reviewed clinical studies in the record related to the use of the Optune device. Results from a phase III clinical trial utilizing TTFT in patients with recurrent glioblastoma was shown to have equivalent efficacy when compared to the best physician's choice for chemotherapy. (Exh. 2, pp. 101-110). With respect to patients newly diagnosed with glioblastoma, results of a phase III study released in a December 15, 2015, JAMA article showed that adding TTFT to maintenance temozolomide significantly prolonged progression-free and overall survival. (Exh. 3, pp. 369-379). Significantly, patients in the control group in the JAMA-reported study crossed over to the combined therapy group for TTFT treatment due to the improvement in outcomes seen. *Id.* The results from these phase III trials also led to FDA approval for the Optune device. *Id.* Again, these trials showed that the Optune device was safe, non-investigational and effective. In addition, these trials showed that the Optune device was appropriate for this individual Enrollee's needs, specifically the treatment of recurrent glioblastoma.

Third, the use of TTFT is generally accepted by the medical community. In the 2015 version of the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology Central Nervous System Cancers guidelines, alternating electric field therapy is a treatment option suggested for glioblastoma. (Exh. 1, p. 13; Hearing testimony). This suggestion was found in a treatment guideline from a national cancer organization, not evidence based on an individual physician treating a single patient in a clinical setting. As such, this ALJ finds that TTFT treatment is generally accepted in the medical community as safe and effective for the treatment of recurrent glioblastoma.

Overall, a review of the literature available showed that the Optune device received FDA premarket approval, showing that it was safe and effective and not investigational/experimental. The use of the Optune device in a population with recurrent glioblastoma was proven effective and appropriate through a phase III clinical trial; and the use of the Optune device appears in

³<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm>

national cancer treatment guidelines for treatment of glioblastoma, showing general acceptance by the medical community. A number of commercial health plans also now cover TTFT.

The final aspect is the medical record of this specific Enrollee. A review of the medical records and hearing demonstrated that the Enrollee had already undergone surgical resection of the tumor and chemotherapy. When he began treatment with the Optune (TTFT) device, the Enrollee had exhausted other treatment options and his disease continued to recur and progress. This Enrollee had no feasible alternative pattern of care available to him to halt the progression of his disease. For the Enrollee, the preponderance of the evidence is that the TTFT therapy was medically reasonable and necessary for the treatment of his condition.

For the reasons stated above, this ALJ finds that Optune (TTFT) has been shown to be safe and effective and was medically reasonable and necessary for the treatment of this Enrollee's condition for the dates of service in question.

Conclusions of Law


This decision is **FULLY FAVORABLE** for the Appellant/Enrollee. This Administrative Law Judge decides that the Plan must pre-approve the use of the Optune device using tumor treatment field therapy (TTFT). Therefore, the Plan shall cover the related care received by the Enrollee from February 27, 2017, to March 31, 2017.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated: AUG 02 2017


Aaron R. Raff
U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City, MO

Appeal of: [REDACTED]

ALJ Appeal No.: 1-6210417199

Beneficiary: [REDACTED]

Medicare: Part C

HICN: *****9958A

Before: Aaron Raff
Administrative Law Judge

EXHIBIT LIST

EXHIBIT NUMBER	DESCRIPTION	PAGE NUMBERS
1	Organization Determination, MAO Reconsideration and Part C QIC Reconsidered Decision Procedural Documents	24
2	Medical Records/Evidence received by MAO and CMS contractors	119
3	Evidence of Coverage	388
4	Request for ALJ Hearing	02
5	OMHA Proceedings	38

Dated: August 2, 2017

REQUEST FOR REVIEW OF ADMINISTRATIVE LAW JUDGE (ALJ) MEDICARE DECISION / DISMISSAL

1. APPELLANT (the party requesting review) 2. ALJ APPEAL NUMBER (on the decision or dismissal)

3. BENEFICIARY* 4. HEALTH INSURANCE CLAIM NUMBER (HICN)*

*If the request involves multiple claims or multiple beneficiaries, attach a list of beneficiaries, HICNs, or other information to identify all claims being appealed.

5. PROVIDER, PRACTITIONER, OR SUPPLIER 6. SPECIFIC ITEM(S) OR SERVICE(S)

7. Medicare claim type: ☐ Part A ☐ Part B ☐ Part C - Medicare Advantage
☐ Part D - Medicare Prescription Drug Plan ☐ Entitlement/enrollment for Part A or Part B

8. Does this request involve authorization for an item or service that has not yet been furnished?

☐ Yes If Yes, skip to Block 8.
☐ No If No, Specific Dates of Service:

9. If the request involves authorization for a prescription drug under Medicare Part D, would application of the standard appellate timeframe seriously jeopardize the beneficiary's life, health, or ability to regain maximum function (as documented by a physician) such that expedited review is appropriate? ☐ Yes ☐ No

I request that the Medicare Appeals Council review the ALJ's ☐ decision or ☐ dismissal order [check one] dated _____. I disagree with the ALJ's action because (specify the parts of the ALJ's decision or dismissal you disagree with and why you think the ALJ was wrong):

(Attach additional sheets if you need more space)

PLEASE ATTACH A COPY OF THE ALJ DECISION OR DISMISSAL ORDER YOU ARE APPEALING.

DATE			DATE		
APPELLANT'S SIGNATURE (the party requesting review)			REPRESENTATIVE'S SIGNATURE (include signed appointment if not already submitted.)		
PRINT NAME			PRINT NAME		
ADDRESS			ADDRESS		
CITY, STATE, ZIP CODE			CITY, STATE, ZIP CODE		
TELEPHONE NUMBER	FAX NUMBER	E-MAIL	TELEPHONE NUMBER	FAX NUMBER	E-MAIL

(SEE FURTHER INSTRUCTIONS ON PAGE 2)

If you have additional evidence, submit it with this request for review. If you need more time, you must request an extension of time in writing now, explaining why you are unable to submit the evidence or legal argument now.

If you are a provider, supplier, or a beneficiary represented by a provider or supplier, and your case was reconsidered by a Qualified Independent Contractor (QIC), the Medicare Appeals Council will not consider new evidence related to issues the QIC has already considered unless you show that you have a good reason for submitting it for the first time to the Medicare Appeals Council.

IMPORTANT: Include the HICN and ALJ Appeal Number on any letter or other material you submit.

This request must be received within 60 calendar days after you receive the ALJ's decision or dismissal, unless we extend the time limit for good cause. We assume you received the decision or dismissal 5 calendar days after it was issued, unless you show you received it later. If this request will not be received within 65 calendar days from the date on the decision or dismissal order, please explain why on a separate sheet.

You must file your request for review in writing with the Medicare Appeals Council at:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

You may send the request for review by U.S. Mail, a common carrier such as FedEx, or by fax to (202) 565-0227. If you send a fax, please do not also mail a copy. **You must send a copy of your appeal to the other parties and indicate that all parties, to include all beneficiaries, have been copied on the request for review. For claims involving multiple beneficiaries, you may submit a copy of the cover letters issued or a spreadsheet of the beneficiaries and addresses who received a copy of the request for review.**

If you have any questions about your request for review or wish to request expedited review of a claim involving authorization of your prescription drug under Medicare Part D, you may call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100. You may also visit our web site at www.hhs.gov/dab for additional information on how to file your request for review.

PRIVACY ACT STATEMENT

The collection of information on this form is authorized by the Social Security Act (section 205(a) of title II, section 702 of title VII, section 1155 of Title XI, and sections 1852(g)(5), 1869(b)(1), 1871, 1872, and 1876(c)(5)(B) of title XVIII, as appropriate). The information provided will be used to further document your claim. Information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your claim. Information you furnish on this form may be disclosed by the Department of Health and Human Services or the Social Security Administration to another person or governmental agency only with respect to programs under the Social Security Act and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services, the Social Security Administration, or other agencies.



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Miami, Florida

Appeal of:

OMHA Appeal No.: **1-8088112572**

Enrollee:

Medicare: **Part C**

Medicare No.: *******4742A**

Before: **Gerald Foulds**
Administrative Law Judge

DECISION

After carefully considering the evidence presented in the record, a **FAVORABLE** decision is entered for the Appellant/Enrollee ('Enrollee').

PROCEDURAL HISTORY

The Enrollee's physician submitted a request to Humana ("Plan") for pre-approval of Tumor Treatment Field Therapy ("TTFT") (E0766) to treat Enrollee's left temporal lobe glioblastoma. Upon initial determination, the Plan denied the request, finding that TTFT is not considered medically reasonable and necessary. The Enrollee's physician filed an appeal with the Plan, and the Plan upheld the denial. Upon reconsideration, Maximus Federal Services, a Medicare Part C Qualified Independent Contractor ("QIC"), issued an unfavorable decision, finding that the Plan does not have to pre-approve TTFT. (Exh. 1, pp. 3-4).

On November 9, 2018, the Office of Medicare Hearings and Appeals ("OMHA") received Novocure, Inc.'s ("Provider") Administrative Law Judge ("ALJ") Hearing Request Form. (Exh. 3, p. 1). The request was timely, and the amount in controversy satisfies the jurisdictional requirement for an ALJ hearing pursuant to Section 1869(b)(1) of the Social Security Act ("Act").

On February 4, 2019, a telephonic hearing was held before the ALJ in Miami, Florida. (Hearing CD). Julie Miles, R.N. ("Ms. Miles"), Dan McCoy ("Mr. McCoy"), and Syed Ali ("Mr. Ali"), all from Novocure, and Simon Khagi, M.D. ("Dr. Khagi") appeared on behalf of the Enrollee, and waived the right to legal representation. (*Id.*) Marcia Taylor ("Ms. Taylor"), and Bryan Carr, M.D. ("Dr. Carr") appeared on behalf of the Plan. (*Id.*) The record includes Exhibits 1 through 4, which were admitted without objection, Exhibit 5, which was admitted for good cause, and the recorded hearing testimony.

ISSUE

Whether the Plan is required to pre-approve Tumor Treatment Field Therapy ("TTFT") (E0766) to treat Enrollee's left temporal lobe glioblastoma.

FINDINGS OF FACT

After careful consideration of the entire record (Exhibit List attached and incorporated herein), a preponderance of the evidence establishes the following facts:

The Enrollee, a male, was 72 when the Optune device was requested. (Exh. 2, p. 5). In March 2017, Enrollee was hospitalized after experiencing seizures. (Exh. 2, p. 6). Magnetic resonance imaging ("MRI") scans showed that he had a left temporal lesion. (*Id.*) In April 2017, the Enrollee underwent a craniotomy with gross total resection of the lesion, and a pathology report revealed results consistent with a left temporal glioblastoma (WHO IV). (*Id.*)

The Enrollee underwent postoperative standard brain radiation therapy. (Exh. 2, p. 7). He was in a maintenance course of temozolomide, and had used the Optune TTFT along with temozolomide with good result. (Exh. 2, pp. 6-7). In August 2018, the Enrollee's physician wrote a renewal prescription for the Optune device, to be used in conjunction with temozolomide to treat Enrollee's newly-diagnosed glioblastoma. (Exh. 2, p. 1; Hearing CD). The Enrollee used the Optune device, with three dates of service from July 6, 2018 through October 8, 2018. (Hearing CD).

The Center for Devices and Radiological Health of the Food and Drug Administration ("FDA") has approved the use of the Optune tumor treatment field device as a treatment for adult patients with histologically-confirmed glioblastoma multiforme with temozolomide for newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy. (Exh. 5). The Journal of the American Medical Association has published studies that support the addition of tumor-treating fields to standard therapy in patients with glioblastoma. (Exh. 5).

The National Comprehensive Cancer Network ("NCCN") guidelines, version 1.2018, references adjuvant temozolomide plus alternating electric field therapy (Optune) and concurrent radiation and temozolomide as "category 1" treatment for glioblastoma. (Hearing CD). Category 1 treatment indicates that the NCCN recommendation was based on a high level of evidence, and there was uniform consensus on the NCCN panel that approved the therapy. (*Id.*)

In August 2018, the Centers for Medicare and Medicaid Services ("CMS") addressed a request for formal reconsideration of the TTFT Local Coverage Determination ("LCD") coverage criteria. (Exh. 5). CMS stated that coverage of newly diagnosed glioblastoma is not addressed by the LCD, and the request to add coverage for newly diagnosed glioblastoma is valid. (*Id.*)

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

Plan determinations are subject to appeals procedures set forth under the Medicare Advantage Program, also known as Medicare Part C.

An enrollee who receives an adverse Medicare Advantage (“MA”) plan determination, including the MA organization’s refusal to provide or pay for services in whole or part, is entitled to a Reconsideration by the MA organization, and if not thereafter satisfied, to a subsequent Reconsideration to be performed by an Independent Review Entity (“IRE”). *See* Act § 1852(g); 42 C.F.R. §§ 422.566 and 422.576 – 422.596. Enrollees dissatisfied with the IRE’s Reconsideration are entitled to a hearing before the Secretary of the Department of Health and Human Services (“HHS”), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. *See* Act § 1852(g)(5); 42 C.F.R. §§ 422.600 – 422.602.

In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005); 42 C.F.R. §§ 422.600 - 422.602 and 422.626. The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005); 42 C.F.R. § 422.608.

For requests for ALJ hearing filed in calendar year 2018, the minimum amount remaining in controversy required for an ALJ hearing is \$160.00 (following application of any co-insurance or deductible). *See* Act § 1869(b)(1)(E); 82 Fed. Reg. 45592 (Sep. 29, 2017); 42 C.F.R. §§ 405.1006(b), 405.1006(d)(1)(ii) and 422.600.

To be considered timely, the request for hearing must be received by OMHA within sixty days after the Appellant receives the reconsideration decision. *See* 42 CFR §405.1002(a)(1). The Appellant is presumed to have received the QIC’s reconsideration five days after the date noted on the first page of the reconsideration, unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3).

B. Scope of Review

In hearing appeals under Medicare Part C, the ALJ generally applies the same administrative review and hearing processes that are employed in reviewing cases under Medicare Parts A and B. 42 C.F.R. § 422.562(d).

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration and that were not decided entirely in [the Appellant’s] favor. 42 C.F.R. § 405.1032(a). However, if evidence presented before or during the hearing causes the ALJ to question a favorable portion of the determination, he or she notifies the parties before the hearing and may consider it an issue at the hearing. (*Id.*)

An Appellant may offer new evidence for the first time at the ALJ level only upon a showing of good cause why the evidence was not submitted to the QIC or a prior decision maker. *See* 42 C.F.R. §§ 405.1018, 405.1028 and 405.1030. The ALJ will determine whether good cause exists for the late submission of the new evidence and may only consider the evidence in making a decision if good cause is found. *See (Id.)* This late evidence restriction does not apply to unrepresented beneficiaries. *See* 42 C.F.R. § 405.1018(d).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue and issues a decision based on the hearing record. 42 C.F.R. § 405.1000(d). *De novo* review requires the ALJ to review and evaluate the evidence without regard to the findings of prior determinations on the claim and make an independent assessment relying upon the evidence and controlling laws. All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Act and applicable implementing regulations, are binding on ALJs. 42 C.F.R. § 405.1063(a).

The Appellant has the burden of proving each element of a Medicare claim by preponderance of the evidence. *See* Act §§ 1814(a)(1), 1815(b), and 1833(e); 42 C.F.R. § 424.5(a)(6); 42 C.F.R. §§ 405.1018, 405.1028 and 405.1030.

The ALJ may decide a case on the record and not conduct an oral hearing if all the parties indicate in writing that they do not wish to appear before the ALJ at an oral hearing. *See* 42 C.F.R. § 405.1038(b)(1)(i). In addition, if the evidence in the record supports a finding in favor of the Appellant on every issue, the ALJ may decide a case without a hearing. *See* 42 C.F.R. § 405.1038(a).

Unless the ALJ dismisses the hearing, the ALJ will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. 42 C.F.R. § 405.1046(a). The decision must be based on evidence offered at the hearing or otherwise admitted into the record. (*Id.*)

II. Principles of Law

A. Statutes and Regulations

The Medicare program, Title XVIII of the Act, is administered through CMS. The Medicare Part C program allows public and private organizations to contract with CMS to provide beneficiaries with Medicare Part A and Part B benefits through a variety of Medicare Advantage (“MA”) health plans. Section 1812 of the Act sets forth the scope of benefits of the hospital insurance program under Medicare Part A. Section 1814 of the Act establishes conditions of, and limitations on, payment for services. Section 1831 of the Act establishes the supplementary medical insurance program for the aged and the disabled, known as Medicare Part B. Section 1832 of the Act sets forth the scope of benefits furnished under the Medicare Part B supplementary medical insurance program. Section 1851 of the Act establishes the eligibility, election and enrollment requirements of Medicare Part C. Section 1852 of the Act sets forth the benefits and beneficiary protections under Medicare Part C.

A MA plan must make available to an enrollee, or provide reimbursement for, at least all services covered under Part A and Part B of Medicare, and may provide for payment of additional services if specified in the MA plan's policy. *See* Act § 1852; 42 C.F.R. § 422.101.

MA plans must pay for medical services or equipment if Medicare would cover the service or equipment. 42 C.F.R. § 422.101. Under Medicare Part B, a beneficiary is entitled to have payment made on his behalf for medical and other health services. Act § 1832(a)(1). The Act provides that Medicare pays for the rental or purchase of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") if the equipment is used in the patient's home or in an institution that is used as a home. *See* Act § 1832(a)(1), (a)(2)(B), (a)(2)(I), 1834(a)(13), 1861(s)(6) and 1861(11)); 42 C.F.R. § 410.3.

An MA plan may select networks of providers from whom members can receive services. 42 C.F.R. § 422.112. If original Medicare covers a service only when certain conditions are met, then these conditions must be met in order for the service to be considered part of the original-Medicare-benefits component of an MA plan. An MA plan may cover the same service when the conditions are not met but these benefits would then be defined as supplemental. CMS, *Medicare Managed Care Manual (MMCM) (Internet-Only Manual Publ'n 100-16)* ch. 4, §30.2. An MA plan may create supplemental benefits, either mandatory or optional, regarding coverage. *MMCM supra* ch. 4, § 20.23.

MA organization health plans must provide coverage for all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B). Further, MA plans must comply with national coverage determinations (NCDs) as promulgated by CMS. 42 C.F.R. § 422.101. MA organizations must disclose to each beneficiary enrolling in an MA plan offered by the organization a detailed content of plan description, including, but not limited to, the plan's service area, benefits, access, out-of-area coverage, emergency coverage, premiums and cost sharing (such as co-payments, deductibles and coinsurance). This information must be offered at the time of enrollment and at least annually after that, in a clear, accurate and standardized form. 42 C.F.R. § 422.111. MA organizations may specify the networks of providers from whom enrollees may obtain services as long as the MA organization ensures that all covered services, including additional or supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan with reasonable promptness and in a manner which assures continuity in the provision of benefits. Act § 1852 (d); 42 C.F.R. § 422.112.

Section 1862(a) of the Act states, in pertinent part: "[n]otwithstanding any other provision of this title, no payment may be made under Part A or Part B for any expenses incurred for items or services -- (1)(A) which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" Act § 1862(a)(1)(A); *see* 42 C.F.R. § 411.15(k)(1).

B. Policy and Guidance

Section 1871(a)(2) of the Act states that, unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than a National Coverage Determination ("NCD"), can establish or change a substantive legal standard governing the scope of benefits or payment for

services under the Medicare program. Section 1869(f)(1) of the Act provides that an NCD is binding upon an ALJ. *See* 42 C.F.R. § 405.1060(a)(4).

In lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local medical review policies (“LMRPs”) or local coverage determinations (“LCDs”). Section 1869(f)(2) of the Act provides that an ALJ will give substantial deference to LCDs, LMRPs, or CMS program guidance when applicable. *See also* 42 C.F.R. §405.1062. If an ALJ declines to follow such guidance in a particular case, the ALJ must explain the reasons for not following the policy in his or her decision. (*Id.*).

The Medicare Benefit Policy Manual sets forth detailed guidelines relating to the necessity for and reasonableness of durable medical equipment. *See* CMS, *Medicare Benefit Policy Manual (MBPM)* (Internet-Only Manual Publ’n 100-02) ch. 15, § 110.

The Medicare Program Integrity Manual sets forth the CMS requirements with which contractors must comply when drafting LCDs, and the criteria that contractors must use in determining whether a service is reasonable and necessary. *See* CMS, *Medicare Program Integrity Manual (MPIM)* (Internet-Only Manual Publ’n 100-08) ch. 13, § 13.5.4.

The Medicare Managed Care Manual sets forth detailed coverage guidelines relating to benefits and beneficiary protections under Medicare Part C. *See MMCPM supra* ch. 4.

Relevant to this appeal is LCD L34823, which was promulgated by Medicare Contractors CGS Administrators, LLC and Noridian Healthcare Solutions, LLC, and became effective January 1, 2017 and as currently in effect, states that “Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.”

Also relevant to this appeal is the Plan’s Evidence of Coverage for 2018. (Exh. 1).

ANALYSIS

After a thorough review of the record, the undersigned finds that the Enrollee was entitled to pre-approval for Tumor Treatment Field Therapy (“TTFT”) (E0766) to treat Enrollee’s left temporal lobe glioblastoma. The QIC found that the Plan does not have to pre-approve TTFT because TTFT is not considered medically reasonable and necessary under the applicable LCD. (Exh. 1, pp. 3-4).

A MA plan must provide an enrollee with coverage for all items and services covered by Medicare Part A (except hospice services) and Part B that are available to beneficiaries in the plan’s service area. *See* Act § 1852(a)(1); 42 C.F.R. §§ 422.100(c)(1) and 422.101(a). Coverage is also governed on a national basis by manuals issued by CMS, as well as by NCDs. Medicare Administrative Contractors for Medicare Parts A and B may issue LCDs and other guidelines, which further define and explain local coverage policies for the particular geographical area that the Contractor oversees. A MA plan must comply with NCDs, LCDs, and general coverage guidelines included in original Medicare manuals. *See* 42 C.F.R. § 422.101(b). Both Medicare and the Plan’s Evidence of Coverage require that Medicare covered services be provided according to the coverage guidelines established by Medicare, and that the services must be medically necessary, that is,

reasonable and necessary for the prevention, diagnosis or treatment of a medical condition. *See* Act § 1862(a)(1)(A); *see* 42 C.F.R. § 411.15(k)(1).

Local Coverage Determination L34823, promulgated by Medicare Contractors CGS Administrators, LLC and Noridian Healthcare Solutions, LLC, which became effective January 1, 2017 and as currently in effect, states that “Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary”. Pursuant to 42 C.F.R. § 405.1062(a) an ALJ is not bound by contractor LCDs or CMS program guidance, such as program memoranda and manual instructions, “but will give substantial deference to these policies if they are applicable to a particular case.” An ALJ must explain the reason for not following such a policy in a specific case. 42 C.F.R. § 405.1062(b). Any decision to disregard a policy “applies only to the specific claim being considered and does not have precedential effect.” (*Id.*)

After a careful and thorough review of the arguments and the evidence in the record, the undersigned has declined to follow the applicable LCD¹ in light of FDA approval, peer-reviewed medical literature, general acceptance by the medical community and the specific evidence of medical necessity in this case. (Exh. 5). Preliminarily, the undersigned finds that the LCD does not specifically address coverage of newly diagnosed glioblastoma. In fact, in August 2018, CMS addressed a request for formal reconsideration of the TTFT LCD coverage criteria. (Exh. 5). CMS stated that coverage of newly diagnosed glioblastoma is not addressed by the LCD, and the request to add coverage for newly diagnosed glioblastoma is valid. (*Id.*) In addition, the submitted documentation confirms the FDA’s pre-market approval of the Optune device for newly diagnosed glioblastoma in combination with temozolomide after standard surgical resection and radiation therapy. (Exh. 5). Articles from the Journal of the American Medical Association support the addition of tumor-treating fields to standard therapy in patients with glioblastoma. (*Id.*) Furthermore, the National Comprehensive Cancer Network issued a level 1 recommendation that TTFT should be used to treat glioblastoma. (*Id.*)

The ALJ finds that the Optune device is medically reasonable and necessary for the Enrollee. In the instant appeal, the Enrollee, a then 72 year old male was diagnosed with a left temporal glioblastoma (WHO grade IV)². (Exh. 2, p. 6). Prior to his diagnosis, the Enrollee was experiencing seizures. (*Id.*) MRI scans showed that he had a left temporal lesion. (*Id.*) The Enrollee underwent a craniotomy with gross total resection of the lesion, and a pathology report revealed results consistent with a left temporal glioblastoma. (*Id.*) The Enrollee underwent postoperative standard brain radiation therapy. (Exh. 2, p. 7). He was in a maintenance course of temozolomide, and had used the Optune TTFT along with temozolomide with good result. (Exh. 2, pp. 6-7). In August 2018, the Enrollee’s physician wrote a renewal prescription for the Optune device, to be used in conjunction with temozolomide to treat Enrollee’s newly diagnosed glioblastoma. (Exh. 2, p. 1; Hearing CD). The Enrollee used the Optune device, with three dates

¹ The undersigned notes that although LCD L34823 sets out a categorical denial of TTFT, it does not cite any research or other information that leads to the Contractor’s conclusion that the Optune is never medically reasonable and necessary. Contractor LCDs should be based on the strongest evidence available, including randomized clinical studies.

² **Glioblastoma (GBM)** is an aggressive type of cancer that can occur in the brain or spinal cord. GBM tumors form from cells called astrocytes that support nerve cells. GBM can occur at any age but tends to occur more often in older adults, and can cause worsening headaches, nausea, vomiting and seizures. GBM, also known as glioblastoma multiforme, can be very difficult to treat and a cure is often not possible. Treatments may slow progression of the cancer and reduce signs and symptoms (*See* Mayo Clinic at <https://www.mayoclinic.org/diseases-conditions/glioblastoma/cdc-20350148>).

of service from July 6, 2018 through October 8, 2018. (Hearing CD). The Enrollee's treatment plan is in line with the FDA approval, peer-reviewed medical literature and standard of care generally accepted by the medical community.

Based on the foregoing, the undersigned finds that the Enrollee was entitled to pre-approval for Tumor Treatment Field Therapy ("TTFT") (E0766) to treat Enrollee's left temporal lobe glioblastoma.

CONCLUSIONS OF LAW

Humana is required to grant pre-approval and cover the Tumor Treatment Field Therapy ("TTFT") (E0766) to treat Enrollee's left temporal lobe glioblastoma.

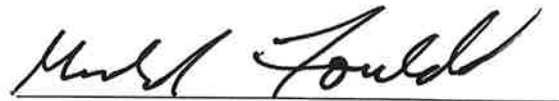
ORDER

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED

FEB 25 2019

Dated:



Gerald Foulds
Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Miami, Florida

Appeal of:

OMHA Appeal No.: **1-6983357272**

Enrollee:

Medicare: **Part C**

HICN: *******5321A**

Before: **Donna Dickens**
Administrative Law Judge

ON-THE-RECORD DECISION

After carefully considering the evidence and arguments presented in the record and at hearing, a **FULLY FAVORABLE** on-the-record decision is entered for the Appellant/Enrollee,

Procedural History

The Enrollee, , sought pre-approval for Medicare, Part C coverage of an electrical stimulation device. The Enrollee's Medicare Advantage Plan ("MA Plan"), HUMANA INSURANCE COMPANY (HUMANA), denied coverage through redetermination. MAXIMUS, a Medicare Qualified Independent Contractor ("QIC"), upheld the denials upon reconsideration review on November 9, 2017.

By correspondence received November 16, 2017, Appellant requested a hearing before an Administrative Law Judge ("ALJ") of the Office of Medicare Hearings and Appeals ("OMHA").

Following review of the record, the undersigned finds a favorable decision is warranted. Thus, the undersigned is issuing this decision without a hearing as permitted under 42 C.F.R. §405.1038(a). All exhibits were admitted into the record.

Issues

The issue presented is whether the MA Plan is required to cover the Enrollee's electrical stimulation device under Medicare, Part C.

Findings of Fact

After careful consideration of the entire record (Exhibit List attached and incorporated herein), a preponderance of the evidence establishes the following facts:

1. The Enrollee, an 80-year old male, has a medical history significant for glioblastoma ("GBM"). (Ex. 2, p. 4). He also has a medical history significant for anemia, atrial fibrillation, coronary artery disease, prostate cancer, cataracts, hyperlipidemia, hypertension, inguinal hernia without mention of obstruction or gangrene, unilateral or unspecified, and osteoarthritis. *Id.*
2. On October 18, 2017, the Enrollee's physician, Richard Curry, M.D., prepared a correspondence to the MA Plan. (Ex. 2, p. 1).
 - a. According to the correspondence, the Enrollee initially presented with hiccups followed by confusion. *Id.*
 - b. Neuroimaging revealed a right temporal lobe mass. *Id.* He underwent a subtotal resection on June 2, 2017 and pathology was consistent with GBM. *Id.*
 - c. The Enrollee underwent chemo therapies from July 6, 2017 through July 24, 2017. *Id.*
 - d. As of October 18, 2017, the Enrollee continued to experience random visual hallucinations. *Id.*
 - e. As a result of the aforementioned, the physician decided to prescribe Optune for the Enrollee in combination with temozolomide as the best treatment to treat the Enrollee's GBM. *Id.*
 - f. The physician explains that the alternating electric field therapy (Optune) and adjuvant temozolomide is now an NCCN Category 2A recommendation following postoperative standard brain radiation therapy. *Id.*
3. The record included an Article from the Journal of the American Medical Association titled *Maintenance Therapy with Tumor-Treating Fields Plus Temozolomide Alone for Glioblastoma* with the original print date December 15, 2015. (Ex. 2, pp. 28-37). The record also included an Article from the National Comprehensive Cancer Network ("NCCN") Clinical Practice Guidelines in Oncology for Central Nervous System Cancers, Version 1, 2016. (Ex. 2, pp. 38-41).
4. Optune received pre-market approval from the FDA for recurrent GBM in April 2011 based on the results of a large randomized controlled trial of patients with recurrent GBM comparing Optune as a monotherapy to standard chemotherapy used in recurrent GBM. (Ex. 2, p. 1). In 2015, Optune received pre-market approval from the FDA for newly diagnosed GBM in combination with temozolomide after standard surgical resection and radiation therapy. (Ex. 2, p. 2).
5. The QIC denied coverage finding that the MA plan was not required to pre-approve the electrical stimulation device. (Ex. 1, p. 5). The QIC provided that tumor treatment field therapy (E0766) is not considered medically reasonable or necessary, pursuant to LCD L34823. *Id.*

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) § 1869(b)(1)(A).

In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. See 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *Id.*

A hearing before an ALJ is only available if the remaining amount in controversy is \$150 or more for requests filed in calendar year 2015. See 79 Fed. Reg. 57934 (Sep. 26, 2014). The request for hearing is timely if filed within sixty days after receipt of the reconsideration determination. See 20 C.F.R. § 404.933(b)(1).

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in the Appellant's favor; however, if evidence presented before or during the hearing causes the ALJ to question a fully favorable decision, the Appellant will be notified and it will be considered an issue at hearing. 42 C.F.R. § 405.1032(a).

The ALJ may decide a case on the record and not conduct an oral hearing if the evidence in the hearing record supports a finding in favor of appellant(s) on every issue, or if the Appellant and all parties indicate in writing that they do not wish to appear before the ALJ at oral hearing. 42 C.F.R. § 405.1038.

The burden of proving each element of a Medicare claim lies with the Appellant by preponderance of the evidence (i.e. satisfied through the submission of sufficient evidence in accordance with Medicare rules). See Sections 1814(a)(1), 1815(b), and 1833(e) of the Act; 42 C.F.R. § 424.5(a)(6), 42 C.F.R. § 405.1018, 42 C.F.R. § 405.1028, and 42 C.F.R. § 405.1030. All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Social Security Act and applicable implementing regulations, are binding on ALJ's. 42 C.F.R. § 405.1063.

An Appellant may offer new evidence for the first time at the ALJ level of appeal only upon a showing of good cause why the evidence was not submitted to the QIC or a prior decision maker. The ALJ will determine whether good cause exists for the late submission of the new evidence and may only consider the evidence in making a decision if good cause is found. See 42 C.F.R. § 405.1018, 42 C.F.R. § 405.1028 and 42 C.F.R. § 405.1030. This late evidence restriction does not apply to unrepresented beneficiaries. See 42 C.F.R. § 405.1018(d).

Unless the ALJ dismisses the hearing, the ALJ will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. 42 C.F.R. § 405.1046(a). The decision must be based on evidence offered at the hearing or otherwise admitted into the record. *Id.*

C. Standard of Review

The ALJ conducts a de novo review of each claim at issue and issues a decision based on the hearing record. 42 C.F.R. § 405.1000(d) and Section 557 of the Administrative Procedure Act. De novo review requires the ALJ to review and evaluate the evidence without regard to the findings of prior determinations on the claim and make an independent assessment relying upon the evidence and controlling laws.

II. Principles of Law

A. Social Security Act

The Medicare Program, Title XVII of the Act (42 U.S.C. §§1395-139ggg) is administered through CMS. The Secretary of the Department of Health and Human Services is authorized to enter into contracts with private entities for the day-to-day operations of the program, §1842(a)(1)(A) of the Act.

The MA program (Part C of the Act) provides that a MA organization offering a MA plan must provide enrollees, at a minimum, with all basic Medicare-covered services by furnishing the benefits directly or through arrangements, or by paying for the benefits. Basic benefits are benefits defined as “all Medicare covered services, except hospice services.” Mandatory supplemental benefits are defined as “services not covered by Medicare that an MA enrollee must purchase as part of an MA plan that are paid for in full, directly by (or on behalf of) Medicare enrollees, in the form of premiums or cost sharing. Optional supplemental benefits are defined as “health services not covered by Medicare that are purchased at the option of the MA enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost sharing. These services may be grouped or offered individually.” §1852(a) of the Act, 42 CFR §422.100

MA organization health plans must provide coverage for all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B). Further, MA's must comply with national coverage determinations as promulgated by the Centers for Medicare and Medicaid Services. 42 CFR §422.101. MA organizations must disclose to each beneficiary enrolling in a MA plan offered by the organization a detailed content of plan description, including, but not limited to, the plan's service area, benefits, access, out-of-area coverage, emergency coverage, premiums and cost sharing (such as co-payments, deductibles and coinsurance). This information must be offered at the time of enrollment and at least annually after that, in a clear, accurate and standardized form. 42 CFR 422.111. MA organizations may specify the networks of providers from whom enrollees may obtain services as long as the MA organization ensures that all covered services, including additional or supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan with reasonable promptness and in a manner

which assures continuity in the provision of benefits. §1852 (d) of the Act; 42 U.S.C § 1395w-22(d); 42 CFR §422.112.

Notwithstanding any other provision of Title XVIII of the Act, Section 1862(a) of the Act [42 U.S.C. § 1395y(a)(1)(A)] limits the payments that may be made under Part A or Part B, stating in pertinent part that, “no payment may be made under Part A or Part B for any expenses incurred for items or services — (1)(A) which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . .” *Id.*; See also 42 CFR § 411.15(k)(1.) Additionally, § 1833(e) of the Act [42 U.S.C. § 1395l(e)] prohibits Medicare payment for any claim that lacks such information as may be necessary in order to determine the amounts due such provider.

B. Policy and Guidance

Section 1871(a)(2) of the Act states that no rule, requirement, or statement of policy can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program unless it is promulgated as a regulation by CMS, with the only exception being national coverage determinations (NCDs). See 42 CFR § 405.1060. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance describing the criteria for coverage of selected items and services in the form of manuals and local coverage determinations (LCDs), respectively.

i. LCD L34823: Tumor Treatment Field Therapy (TTFT)

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding “reasonable and necessary” criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the “reasonable and necessary” criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the “reasonable and necessary” criteria, based on Social Security Act §1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

C. MA Plan

HUMANA INSURANCE COMPANY (HUMANA)’s 2017 Evidence of Coverage details the services covered by the MA Plan (Ex.1).

Analysis

The Appellant has satisfied the jurisdictional requirements for a hearing before OMHA as the amount in controversy exceeds the requisite amount and the request for hearing was received within 60 days of the reconsideration determination. Having considered the evidence and argument of record, the undersigned finds the request for pre-approval for the electrical stimulation device, should be granted under the Medicare program.

In the instant case, the Enrollee, an 80-year old male, has a medical history significant for GBM. He also has a medical history significant for anemia, atrial fibrillation, coronary artery disease, prostate cancer, cataracts, hyperlipidemia, hypertension, inguinal hernia without mention of obstruction or gangrene, unilateral or unspecified, and osteoarthritis. According to the Enrollee’s physician’s correspondence dated October 18, 2017, the Enrollee initially presented with hiccups followed by confusion. Neuroimaging revealed a right temporal lobe mass. He underwent a subtotal resection on June 2, 2017 and pathology was consistent with GBM. The Enrollee underwent chemo therapies from July 6, 2017 through July 24, 2017. As of October 18, 2017, the Enrollee continued to experience random visual hallucinations. As a result of the aforementioned, the physician decided to prescribe Optune for the Enrollee in combination with temozolomide as the best treatment to treat the Enrollee’s GBM. The physician explains that the alternating electric field therapy (Optune) and adjuvant temozolomide is now an NCCN Category 2A recommendation following postoperative standard brain radiation therapy.

The undersigned has conducted a de novo review of the administrative record and agrees with the Appellant. Pursuant to the applicable LCD, “Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary;” however, the ALJ agrees that the LCD is not binding and does not take into account the educated opinions in the related medical field. The ALJ has taken into account the medical articles presented by the Enrollee’s physician and his assertion that “[a]t the St. Elizabeth Healthcare Cancer Center Optune has been employed successfully for patients such as [Enrollee], and we have achieved excellent results.” The ALJ also notes that based on the material presented, the Enrollee suffers from an orphan disease with limited treatment options, and that Optune in combination with temozolomide appears to be medically necessary and appropriate given the Enrollee’s serious medical condition and that this option has been acknowledged as a safe and effective procedure. Therefore, the undersigned ALJ concludes that pre-approval for the electrical stimulation device should be granted under the Medicare program.

Conclusions of Law


The pre-approval for the electrical stimulation device should be granted under the Medicare program.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED

Dated: JAN 26 2018


Donna Dickens
Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Irvine Field Office
Irvine, CA

Appeal of:	ALJ Appeal No.: 1-7141790809
Beneficiary:	Medicare: Part C [EXPEDITED]
HICN: ***.**1953D6	Before: Michael Cianci U.S. Administrative Law Judge

DECISION

After careful consideration of the evidence and arguments presented, a **FULLY FAVORABLE** decision is entered for (Appellant).

Procedural History

Appellant requested pre-approval coverage from her Plan, Humana Health Plan, Inc., for an electrical stimulation device used for cancer treatment (HCPCS E0766). The tumor treatment field therapy (TTFT) called Optune, is supplied by Novocure, Inc. (Provider). The Plan denied the pre-approval initially and on appeal, on the basis that a Local Coverage Determination (LCD) (L34823) precludes payment. The LCD states TTFT treatments are not medically reasonable and necessary. Independent Review Entity MAXIMUS Federal Services (the IRE) also denied pre-approval of the Optune on the same basis. There was no other basis for the denial and the medical evidence relating to Appellant and her need or eligibility for treatment was not discussed in the denials. Appellant timely filed a timely request for a hearing before an Administrative Law Judge (ALJ) and the amount in controversy meets the jurisdictional requirement for this action. *See* 42 C.F.R. §§ 405.1006 and 422.600(b).

The evidence in the record indicates that Optune is a portable, wearable medical device that delivers TTFT to a targeted tumor. On April 8, 2011, the U.S. Food and Drug Administration (FDA) approved TTFT for treatment of adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme, following histologically or radiologically-confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy and as an alternative to standard medical therapy for glioblastoma multiforme after surgical and radiation options have been exhausted.

In 2015, Optune received additional pre-market approval from the FDA for newly diagnosed glioblastoma in combination with Temozolomide after standard surgical resection and radiation therapy. The Provider is the sole global supplier for the Optune System and they are currently out-of-network for the Plan. Therefore, the treatment is appropriate for both newly diagnosed

and recurrent glioblastoma. The evidence is un rebutted in the medical record that Appellant is eligible for the FDA approved treatment.

Pursuant to proper notice, Appellant's telephonic hearing was scheduled for March 1, 2018. Hearing notice was mailed January 19, 2017. The Plan nor the IRE responded to the notice, nor did either timely submit additional evidence. Pursuant to 42 C.F.R. Sec. 405.1000(g) and 42 C.F.R. Sec. 405.1038(a), the undersigned finds the evidence in the medical record supports a fully favorable decision. Therefore, the undersigned decides this case on the record and the hearing scheduled for March 1, 2018 is vacated.

All Exhibits are admitted into evidence on the record and the undersigned provides excerpts at Exhibit 5, for items he has taken administrative notice of. In this regard, the undersigned takes administrative notice of certain medical literature documents pertaining to TTFT, which are contained on the Novocare website, including medical literature from 2016-present that has greatly adopted the Optune treatment and are supported by numerous clinical studies which establish improved survival rates using the Optune treatment. Moreover, the undersigned finds this recent medical literature supersedes all medical literature which the LCD relied upon at the time.

Furthermore, the undersigned takes administrative notice of the applicable LCD, L34823 and citations to authority, and Medicare Appeals Council (MAC) decision M-15-1354, which involved TTFT, and numerous Novocare press releases which established multiple health plans and nations such as Australia and Japan, now offer Optune coverage as a treatment. One article observing Anthem's positive coverage of Optune touts that more than 97 million Americans are now covered for Optune. Additionally, the undersigned takes administrative notice of recent publications including but not limited to: the *Journal of American Medical Association* (Stupp & Kanner); the *Annual Meeting of the American Association for Cancer Research* (Stupp); and the *World Journal of Surgical Oncology* (Chaudhry, Benson, & Varshaver), amongst others, which reflect positive recommendations for the treatment. These peer review publications tout a significant increase in survival rates using the Optune system in conjunction with Temozolomide for newly diagnosed glioblastoma.¹

Issues

Whether the Plan is required to cover the TTFT (Optune) and whether an out-of-network exception should be granted, if applicable?

Relevant Facts in the Record

The record indicates Appellant, a 77 year old female, requested the Plan to pre-approve coverage for Optune Plus Transducers to treat her glioblastoma. (Exh. 2). Appellant had suffered a seizure on August 23, 2017. She underwent a CT scan of the brain which showed a tumor located in the right anterior frontal lobe with extension into the corpus callosum crossing midline with surrounding edema. She then underwent magnetic resonance imaging (MRI) on August 24,

¹ Blue Cross Blue Shield of Michigan, Japan, Australia, Anthem, and Humana have authorized coverage for the Optune treatment. A news release dated March 3, 2016, observes Humana accepted Optune treatment. A June 5, 2017 article indicates Health Care Service Corporation will now cover Optune. (See Exhibit 5, excerpts).

2017 and the MRI was consistent, showing a 2.9 times 1.8 times 2.1 cm peripherally enhancing mass with surrounding edema. A Brainlab guided biopsy was performed on August 29, 2017 which was reviewed by the Cleveland Clinic, where she had a consultation. Pathology reports confirmed the brain cancer, consistent with "GBM, WHO grade IV (glioblastoma multiforme). (Exh. 2). The treating doctors at Arizona Oncology has prescribed the best course of treatment as being the Optune System in combination with Temozolomide, which according to her treating doctor, Dr. David Vonk, M.D, is medically necessary. (Exh. 2, at 7-9). Additional excision is not recommended due to the location of the tumor. She completed radiotherapy and the treating doctor opines that Optune treatment is her next and best course of treatment. Dr. Vonk highly recommends the Optune treatment and opines it is medically reasonable and necessary for Appellant. The record includes a detailed letter of medical necessity written by Dr. Vonk, which the undersigned finds is highly probative. (Exh. 2, at 7-9).

In addition to the articles described above, the medical record indicates that over 180 health plan payers, including Humana Health, have covered this therapy for certain members after an appeal process. Dr. Vonk also indicated that Optune with Temozolomide is now a National Comprehensive Cancer Network (NCCN) positive Category 2A recommendation following postoperative standard brain radiation therapy with concurrent Temozolomide, meaning the NCCN has recently upgraded its recommendation for the Optune treatment. Given the aggressive nature and extremely limited treatment options of Appellant's disease, Dr. Vonk strongly recommends Appellant receive coverage for Optune, as soon as possible. (Exh. 2, at 7-9).

The medical record also establishes that FDA approved Optune in April 2011 for recurrent glioblastoma, based on the results of a large clinical trial that showed that treatment with Optune delivered comparable overall survival and progression free survival (PFS) to chemotherapy with minimal toxicity and an improvement in patients' quality of life compared to chemotherapy. Dr. Vonk further explained that FDA approval in 2015 for Optune for newly diagnosed glioblastoma in combination with Temozolomide was based on a prospective, randomized, open label, active parallel control trial to compare the effectiveness and safety outcomes of newly diagnosed glioblastoma multiforme patients treated with Optune and Temozolomide to those treated with Temozolomide alone. The results of the trial at the interim analysis showed superior efficacy both in PFS as well as overall survival. Dr. Vonk indicated that the data was so compelling that the independent data monitoring committee recommended the trial be terminated so that patients in the standard of care arm could cross over. The FDA approved the supplemental IDE to allow for crossover of patients on the control arm to the TTFT arm on December 1, 2014. (Exh. 2, at 7-9).

The pre-specified interim analysis of the trial data was conducted on the first 315 patients, representing approximately 50 percent of the targeted study population. The data showed that patients treated with TTFT together with Temozolomide demonstrated a significant increase in PFS compared to Temozolomide alone (PFS of 7.1 months compared to 4.0 months). Patients treated with TTFT together with Temozolomide demonstrated a significant increase in overall survival compared to Temozolomide alone (overall survival of 19.6 months compared to 16.6 months). Additionally, the percentage of patients alive at 2 years with TTFT together with Temozolomide was 43% compared to the 29% of patients using Temozolomide alone. (Exh. 2).

There is no issue that Appellant is medically cleared and qualifies for the Optune treatment. Dr. Vonk confirms this.

The record indicates a copy of the Plan's Evidence of Coverage appears in a CD, but no such CD was forwarded to this appeal level.

In this case, Appellant requests approval of the Optune treatment and approval for an out-of-network exception, if applicable so that Appellant can access Optune under her network benefits.

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an adverse organization determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) § 1859(g)(5); *see* 42 C.F.R. § 422.600. The request for hearing is timely filed if filed within 60 days of the date of notice of a reconsidered determination. 42 C.F.R. § 422.602.

In implementing this statutory directive, the Secretary delegated authority to administer the nationwide hearings and appeals system for the Medicare program to the Office of Medicare Hearings and Appeals (OMHA). *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005). ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *Id.*

B. Scope of Review

Medicare Advantage Organization determinations and appeals are governed by the regulations in 42 C.F.R. §§ 422.560 through 422.626. Unless otherwise noted, the ALJ hearing procedures set forth in 42 C.F.R. §§ 405.1000 through 405.1064 apply to Medicare Advantage appeals, to the extent they are appropriate. 42 C.F.R. § 422.562(d).

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the Appellant's favor. 42 C.F.R. § 405.1032(a). However, if evidence presented before the hearing causes the ALJ to question a favorable portion of the determination, he or she may notify the parties before the hearing and may consider it an issue at the hearing. *Id.*

C. Standard of Review

OMHA is staffed with ALJs who conduct *de novo* hearings. 42 C.F.R. § 405.1000(d). A *de novo* review means the ALJ reviews the evidence without regard to the findings in the prior determinations on the claim and makes an independent assessment based on the evidence and the controlling laws. However, the burden of proving each element of a Medicare claim lies with the appellant and is satisfied by submitting sufficient evidence in accordance with Medicare rules. *See e.g.*, Act §§ 1814(a)(1), 1815(b), and 1833(e); *see also* 42 C.F.R. §§ 424.5(a)(6), 405.1018, 405.1028, and 405.1030.

II. Principles of Law

A. Statutes and Regulations

Eligibility for Medicare benefits is determined under Title XVIII of the Act, 42 U.S.C. § 1801 et seq., and federal regulations set forth in Title 42 of the Code of Federal Regulations.

The Medicare Part C program establishes standards and sets forth the requirements, limitations, and procedures for Medicare services furnished, or paid for, by Medicare Advantage (MA) organizations through MA plans. *See* Act § 1851 *et seq.*; *see also* 42 C.F.R. § 422.1(b) *et seq.* A person is eligible to enroll in Part C if s/he is entitled to Medicare Part A and enrolled in Part B; has not been medically determined to have end-stage renal disease; and meets the applicable residency requirements. *See* Act § 1851(a)(3) – (b); *see also* 42 C.F.R. § 422.50(a).

Generally, an MA plan must provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Parts A and B of Medicare (Original Medicare) and available to beneficiaries residing in the plan's service area. *See* Act § 1852(a)(1); *see also* 42 C.F.R. § 422.101(a). The MAO must disclose the benefits offered under the MA plan, including applicable conditions and limitations, premiums and cost sharing (such as copayments, deductibles, and coinsurance), and any other conditions associated with receipt or use of benefits. 42 C.F.R. § 422.111.

According to section 1862(a)(1)(A) of the Act, no payment may be made under Original Medicare for any expenses incurred for items or services that are “not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” *See* 42 U.S.C. § 1395y(a)(1)(A); *see also* 42 C.F.R. § 411.15(k)(1).

B. Policy and Guidance

Section 1871(a)(2) of the Act provides that no rule, requirement or statement of policy, other than a national coverage determination (NCD), can establish or change a substantive legal standard governing the scope of the benefits or payment for services under the Medicare program unless promulgated as a regulation by CMS. NCDs promulgated by the Secretary of HHS under the authority of Section 1862(a)(1) of the Act dictate the criteria under which Medicare covers specified services, procedures or supplies. NCDs are binding upon ALJs. 42 C.F.R. § 405.1060(a)(4); *see* 42 C.F.R. § 405.1060(b)(1) (“An ALJ may not disregard, set aside or otherwise review an NCD”).

Although not subject to the force and effect of law, CMS and its contractors issue policies, manuals and guidelines that describe criteria for coverage of selected types of medical items and services in the form of manuals and local coverage determinations (LCDs). **42 C.F.R. § 405.1062 states that an ALJ is not bound by LCDs or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. If an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed. An ALJ decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.** (emphasis added).

LCD L34823 entitled “Tumor Treatment Field Therapy (TTFT)” provides that TTFT (E0766) will be denied as not reasonable and necessary.

The undersigned notes that the LCD contains a blanket citation to authorities for support but provides no rationale, discussion or criteria upon which exceptions can be made within the context of the LCD, or upon which the LCD is based. A closer look at the relied upon citations in the LCD are outdated and do not take into account recent studies and the medical community’s acceptance of the Optune treatment, which has greatly expanded over the last two years. Moreover, it does not discuss what authorities it specifically relies upon, nor what the authorities purport to state. This is significant as will be discussed more fully below.

Moreover, Medicare Policy Article A52711 provides additional guidance for TTFT, and seems to provide some inconsistent analysis with the LCD, which purports to allow coverage where appropriate and states, as follows:

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. “reasonable and necessary”). **Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)).** In order for a beneficiary’s equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Code E0766 is in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories. Separate billing of supplies and/or accessories will be denied as unbundling.

Code A4555 is not valid for billing to Medicare. If code A4555 is billed, it will be denied as an invalid code.

CODING GUIDELINES

Code E0766 describes devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers.

This code is inclusive of all associated supplies necessary for the effective use of code E0766 including, but not limited to, transducers/surface electrodes, lead wires, adhesive patches, connectors, conductive gel and skin preps.

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

The accompanying Policy Article A52711 therefore establishes that TTFT is categorized under the Durable Medical Equipment benefit. The article explains that code E0766 describes “devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers.” The article further states that TTFT devices are in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories. While it defers to any applicable LCD it confirms categorically that in particular medical cases such treatments should be found to be medically reasonable and necessary. Additionally, it anticipates that any applicable LCD will provide eligibility criteria and not be a blanket denial for all cases.

Analysis

After careful consideration of the evidence the undersigned finds that the Optune treatment is medically reasonable and necessary for purposes of coverage under Medicare, and that out-of-network coverage is warranted, if applicable, for this particular Appellant. The aforementioned policy letter and the underlying analysis that went into it clearly anticipate that there are medical situations where the Optune treatment would be medically reasonable and necessary, and it can be approved as a Part B DME. While it ultimately defers to any LCD which may be applicable, clearly the policy letter provides policy support that the treatment has merit and may qualify as a covered DME under the Act, in appropriate medical situations. This case is an appropriate medical situation.

The undersigned finds the extensive medical evidence in the record overwhelmingly supports coverage. The medical evidence establishes the Optune treatment is medically reasonable and necessary for Appellant. That evidence starts with her treating doctor, Dr. Vonk, whose medical opinions are deemed highly probative. Appellant has carried her burden of proof. This evidence includes the letter of medical necessity by the treating physician, as well as the Cleveland Clinic Consultation and the extensive treatment records, confirming her diagnosis, and medical eligibility to be treated with the Optune system. Furthermore, the medical record indicates that further excision is not an option for Appellant. The only option now since already undergoing radiotherapy is the Optune treatment, in combination with Temozolomide. The evidence submitted in the file by Dr. Vonk and Novocure including the upgraded recent recommendations for use by the NCCN, is highly probative. Medical literature overwhelmingly supports treatment by Optune in patients like Appellant. The Optune treatment is well accepted in the medical community and is often the last viable resort for glioblastoma patients.

It is also probative and un-rebutted that over 180 health insurers, reaching over 97 million Americans have allowed coverage in appropriate cases. The medical evidence establishes Appellant’s case is an appropriate case for this treatment. (Exhibit 5, excerpts).

To be clear, this appeal addresses whether the Plan is required to cover the Optune treatment at issue, to this particular Appellant. The IRE concluded that the Plan did not have to provide pre-approval for the device based on LCD L34823 that states that TTFT will be denied as not reasonable and necessary. No further rationale is provided and it is un-rebutted that the Optune treatment is medically necessary for the Appellant. The undersigned further finds the application of the LCD is void of any rationale or discussion and the LCD merely cites certain authorities, which on their face, are outdated, and cannot be relied upon in this case, and which do not address the most recent studies, and more recent acceptance of the treatment by numerous health plans, as well as the NCCN positive recommendation for using the Optune treatment. While giving due consideration to the LCD the undersigned finds the LCD should **NOT** be followed in this case.

In weighing the medical evidence and giving due consideration to the LCD, the undersigned finds the extensive medical evidence in the record establishes the Optune treatment in all medical probability will greatly enhance the life span of Appellant. The Plan has provided no medical evidence in the record to cast any doubt about the effectiveness of the treatment, especially as applied to the Appellant. The decision by the Plan and affirmance by the IRE, is based solely upon the LCD general prohibition, and provides no medical analysis of Appellant's medical diagnosis or condition. The denial decisions further ignore the great weight of medical literature and the NCCN recommendation that establishes the Optune treatment is now readily accepted in the medical community. Dr. Vonk has indicated that the requested treatment in this case is medically necessary and reasonable and that Appellant meets the standards for FDA approved treatment, and this evidence is unrebutted.

Further, the Plan does not contain any explanation for how it reached its denial conclusion, nor does the LCD explain its conclusion for providing no exception criteria. The undersigned finds the LCD provides no meaningful rationale to justify blanket denials for the Optune treatment and that it is inconsistent with the aforementioned agency policy letter on this subject. The LCD if applied must be read in conjunction with the policy letter in a common sense manner and allow coverage where medically necessary and reasonable. It is quite a paradox for over 97 million Americans (which includes coverage by Humana health) to now have coverage for the Optune system, yet Medicare will deny coverage?

The undersigned finds that Federal regulations permit an ALJ to decline to follow a local coverage policy in an individual case. 42 C.F.R. Sec. 405.1062. The undersigned therefore has considered, yet declines to defer to LCD L34823 in this case, based upon the medical record.

The undersigned recognizes there is an older MAC decision which reversed one ALJ decision pertaining to TTFT, although this may be an anomaly since the record indicates there are several ALJ decisions in favor for Optune treatment which have apparently not been reversed, as well as a policy letter by the Agency and overwhelming medical literature which recognizes the treatment is effective when used according to FDA approved purposes. In any event, the undersigned finds that case is distinguishable, and the holding in that decision is outdated.

That case, M-15-1534, focused on what it perceived as the ALJ decision striking down the entire LCD. The result in that MAC decision also relied heavily upon the citation to authorities in the LCD, presumably to reach its conclusion that there was some doubt at the time the LCD was enacted, about the effectiveness of the Optune treatment within the medical community. Based upon that record, the MAC found an insufficient medical record was established to support the

ALJ's decision not to defer to the LCD. Certainly, this case and the undersigned's decision herein does not involve a challenge to the LCD (pursuant to Part 426 or otherwise), and the legal stature of the LCD is not an issue here.²

While the LCD validity is not at issue in this case, it is appropriate for the undersigned to analyze any perceived deficiencies in the LCD and its rationale, the current state of the medical community's view of the Optune treatment, and the current validity of the underlying sources cited in the LCD, otherwise the undersigned would never know when to defer or not defer to follow the LCD. In this regard, it is noteworthy that the MAC decision is already over two years old. During 2016 and 2017, the medical community has favorably embraced the Optune treatment. Moreover, the evidence in the record establishes the authorities the LCD relied upon, are now outdated and do not necessarily reflect the consensus of the medical community, especially in light of recent advances and consensus by numerous Plans to cover Optune. (Exh. 5; Exh. 2, at 7-9).

In this context, the sparse nature of any medical reasoning in the LCD provides additional reasons not to follow it here, where the medical evidence in this record is so overwhelming that

² The MAC decision also criticizes the deciding ALJ decision it reversed indicating the decision did not explain the significance of the various medical literature which was admitted into evidence to support the premise that the Optune treatment is effective. The MAC decision infers the medical evidence in that case relied solely upon this medical literature. That is not the situation here. The letter of medical necessity and clinical notes by the treating doctor, in addition to the medical literature and new studies and clinical trials, as well as evidence that a significant number of medical insurance payers now provide coverage for Optune, establish the medical community accepts Optune as a break-through brain cancer treatment. Moreover, the MAC decision indicates in its last paragraph that the LCD will eventually be updated if warranted and if the medical literature substantially establishes the validity of the treatment. However, circumstances have changed since issuance of that decision. The MAC decision was decided over two years ago and the underlying evidentiary record in the ALJ decision goes back even further. The LCD has not been substantially revised towards coverage nor has it addressed the significant medical advances of the Optune treatment. Additionally, the undersigned finds the sources cited in the LCD are outdated and that subsequent revision were in essence pro forma only. Indeed, it appears as though not all of the old sources cited in the LCD even reach the consensus conclusion in the LCD as two of the cited sources cite to the Novocure website and Novocure's safety summary, and a third cites to a Novocure sponsored study, cite source 7, as reflected and commented upon in cite source 11. This source 11 was published by the Australian Government and published in 2009, which pre-dates even FDA approval of Optune. It in fact notes some survival rates based upon two small studies and recommends monitoring the effectiveness of Optune over a 24 month period. In any event, on their face, the citation dates for each source cited in the LCD establishes that they have not been updated. Appellant has no time to await future administrative revisions. It is clear that the LCD has not kept pace with the medical technology and literature, and the LCD cannot be relied upon in this particular case to deny the treatment to Appellant, where all of the admitted medical evidence in this record supports a finding that the treatment is medically reasonable and necessary for this Appellant at this time. It is clear that the treatment has worked for many patients and has been approved by various medical plans in particular cases, and will in all medical probability be successful for Appellant.

in this Appellant's case, the Optune treatment is more likely than not, going to increase her life span survival. It is also significant that since the MAC case was decided additional studies have proven the effectiveness of the Optune treatment during this period, and by the change of position in many medical insurance entities. In the Novocure press releases and website it confirms that additional tens of millions of plan members are now covered for Optune. This adds to positive coverage from such health entities as Anthem, Regence BCBS, Preferred One, Univera Healthcare, Asuris Northwest Health, and Group Health Cooperative Washington and Idaho.

Moreover, a BCBS article, *BCN Provider News* provides: "The safety and effectiveness of TTF therapy is established for the treatment of supratentorial glioblastoma. TTF therapy may be medically necessary when used under the care of a physician, in adults 22 years and older and as an adjunct therapy to standard therapy." (Exh. 5).

Under the regulations, which unlike policy, has the force and effect of law, the undersigned ALJ has the authority to carefully consider the LCD and then elect to depart from it based upon the evidentiary record. Here, the medical evidence in the administrative record supports the finding that for Appellant the Optune treatment is medically reasonable and necessary for this Appellant, at this time.

The Optune treatment has dramatically expanded survival rates for the type of aggressive brain cancer from which Appellant suffers from. The data showed that patients treated with TTFT together with Temozolomide demonstrated a PFS of 7.1 months compared to 4.0 months for patients treated with Temozolomide alone. Patients treated with TTFT together with Temozolomide also demonstrated a significant increase in overall survival compared to Temozolomide alone (overall survival of 19.6 months compared to 16.6 months). The LCD has not been recently updated substantively and therefore does not consider or address these recent break-through results or general acceptance consensus from the medical community and accordingly the undersigned will not defer to it in this particular case. (Exh. 2).

The undersigned therefore finds that the TTFT device known as Optune, is medically reasonable and necessary for Appellant. In addition, the Provider is entitled to an in-network exception if there are no in-network providers of the device. The medical record contains sufficient documentation of Appellant's disease to substantiate the medical reasonableness and necessity for the Optune treatment at issue, satisfying Medicare rules and regulations.

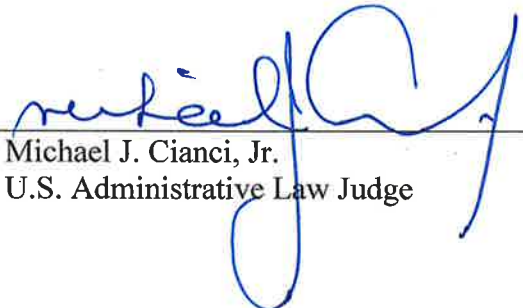
Conclusions of Law and Order

For the reasons above, the Plan and/or its affiliates, is required to provide coverage for the Optune treatment, including if applicable and necessary an out-of-network provider exception.

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated: FEB 14 2018


Michael J. Cianci, Jr.
U.S. Administrative Law Judge



Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

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Date: OCT 24 2018

MELISSA FERNALD
195 COMMERCE WAY
PORTSMOUTH, NH 03801

NOTICE OF DECISION

Appellant: F. STOHL
OMHA Appeal Number: 1-7538272290

Enclosed is the decision for the above case. This decision is based on the administrative record, including any evidence or testimony presented at the hearing, if one was held. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault. In addition, the decision may be reopened within 180 calendar days from the date of the decision for good cause. Good cause exists when there is new and material evidence that was not available or known at the time of the decision and may result in a different conclusion, or when the evidence that was considered clearly shows on its face that an obvious error was made at the time of the decision.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. Other parties may also appeal the decision. In addition, the Medicare Appeals Council may decide to review the decision on its own motion. If no party appeals the decision and the Medicare Appeals Council does not review the decision, the decision is binding on all parties and you and the other parties will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.

How much time do I have to file an appeal?

The Medicare Appeals Council must receive your written appeal **within 60 calendar days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 calendar days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing, except that a request for expedited review of a Part D decision may be made orally as described below. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree.

You may submit a written request for review to the Medicare Appeals Council using one of three available methods: mail, fax, or electronic filing (E-File). **Please do not submit your request for review using more than one method.** Regardless of how you file your appeal, you must always send a copy of your written request for review to the other parties who received a copy of the decision.

If you are filing a written request for review, you may use the enclosed *Request for Review* (form DAB-101), or you may write a letter containing the following:

- The beneficiary's/enrollee's name (and telephone number for Part D appeals);
- The beneficiary's/enrollee's health insurance claim number;
- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's decision;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's decision (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

Filing by mail:

Mail your appeal and a copy of the enclosed decision to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Filing by fax:

Fax your appeal and a copy of the enclosed decision to **(202) 565-0227**.

Filing by computer:

Using your web browser, visit the Medicare Operations Division Electronic Filing System (MOD E-File) website at <https://dab.efile.hhs.gov/mod>.

To file a new appeal using MOD E-File, you will need to register by:

- (1) Clicking **Register** on the MOD E-File home page;
- (2) Entering the information requested on the "Register New Account" form; and
- (3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at <https://dab.efile.hhs.gov/mod/users/new>. You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party's representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

- (1) Logging into MOD E-File;
- (2) Clicking the **File New Appeal** menu button on the top right of the screen;
- (3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
- (4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the "File New Appeal – Medicare Operations Division" form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed decision. All documents should be submitted in Portable Document Format (PDF) whenever possible. Any document, including a Request for Review, will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.

Currently, the documents that may be filed electronically are the:

- (1) Request for Review;
- (2) Appointment of Representative form (OMB Form 0938-0950);
- (3) Copy of Administrative Law Judge or attorney adjudicator decision;
- (4) Memorandum or brief or other written statement in support of your appeal; and
- (5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D decision may be made by telephone to **(866) 365-8204**. You must provide the information listed in the bullet points above and a statement that you are requesting an expedited review within 60 calendar days after receipt of this notice of

decision. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file.

Please note that your request for review will only be expedited if (1) the appeal involves an issue specified in 42 C.F.R. § 423.566(b), but does not include solely a request for payment of a Part D drug that has already been furnished, and (2) the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at <http://www.hhs.gov/dab/>. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll free), if you have questions about filing an appeal.

Enclosures:

OMHA-152, Decision
DAB-101, Request for Review



**Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Miami, Florida**

Appeal of:	F. Stohl	Appeal No.:	1-7538272290
Beneficiary:	F. Stohl		Medicare Part C
HICN:	**6880A	Before:	Michael Amendola
Provider:	Novocure, Inc.		U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, a **FULLY FAVORABLE** decision is entered for F. Stohl ("Appellant").

PROCEDURAL HISTORY

On January 24, 2018, Appellant's pre-approval request for Medicare coverage of Optune, an electrical stimulation device used for cancer treatment, also called tumor treating fields therapy ("TTFT")(billed as E0766), was denied by the Humana Medicare Advantage Plan ("the Plan") as not medically necessary.¹ Upon appeal, the Plan affirmed their denial of payment on May 4, 2013, on the grounds that the treatment is considered to be ineffective, and therefore does not meet the rules for Medicare approval.² Appellant subsequently requested reconsideration from Maximus Federal Services Part C ("the QIC"). On May 8, 2018, the QIC affirmed the unfavorable determination on the same grounds, citing local coverage determination ("LCD"), L34823.³

Appellant subsequently submitted a timely request for hearing before an Administrative Law Judge ("ALJ"), which was received by the Office of Medicare Hearings and Appeals ("OMHA") on May 17, 2016, and the amount in controversy satisfies the jurisdictional requirements for an Administrative Law Judge Hearing pursuant to Title XVIII of the Social Security Act (the Act), §1869(b)(1)(E).⁴

On August 2, 2018, a live telephonic ALJ hearing was held on the matter at OMHA's field office in Miami, Florida, presided by the undersigned ALJ, the Honorable Michael Amendola ("the undersigned"). The provider was present to offer sworn testimony on Appellant's behalf through legal representative Stephanie Hales, Esq. of Sidney, Austin, LLP., with additional testimony provided by Dan McCorry, Novocure Case Management Manager. All exhibits were admitted into evidence without objection. The Plan participated through representatives Marsh Tyler, with additionally medical testimony provided by Dr. Earl Jackman, D.O., Medical Director of Humana. All exhibits were admitted into evidence without objection.

¹ Exhibit 1, page 14.

² Exhibit 1, page 10.

³ Exhibit 1, page 4.

⁴ Exhibit 3, pages 1-5.

ISSUES

Whether Appellant is entitled to Medicare coverage of a portable folding ramp under the durable medical equipment (“DME”) benefit specified under the Title XVIII of the Act, and whether the record supports all Medicare coverage requirements for the DME were met.

LEGAL FRAMEWORK

I. Statutes and Regulations

A party does not have a right to a hearing before an ALJ unless the amount remaining in controversy after a reconsideration decision is issued meets the threshold requirement established annually by the Secretary and published in the *Federal Register*.⁵ For hearing request filed on or after January 1, 2018, a party does not have a right to an ALJ hearing unless the remaining amount in controversy is \$160 after reduction for any Medicare payment already made and any applicable deductible and coinsurance amounts.⁶ The amount in controversy is computed as the actual amount charged the individual for the items and services in question, reduced by any Medicare payment already made and any applicable deductible and coinsurance amounts.⁷

The Administrative Law Judge (ALJ) conducts a *de novo* review and issues a decision based on the record.⁸ *Local Coverage Determination* (LCD) means a decision by a Medicare carrier to cover a particular service under Medicare Part A or Part B.⁹ *National Coverage Determination* (NCD) means a decision that the Centers for Medicare and Medicaid Services (CMS) makes regarding whether to cover a particular service nationally.¹⁰ NCDs are binding on ALJs.¹¹ Although not bound by LCDs or Medicare program policies, the ALJ must give these policies substantial deference.¹² If an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed.¹³

Medicare Part B pays for DME if used in the patient’s home or in an institution that is used as a home.¹⁴ *Durable medical equipment* (DME) means equipment, furnished by a supplier or a home health agency that meets the following conditions: (1) Can withstand repeated use; (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years; (3) Is primarily and customarily used to serve a medical purpose; (4) Generally is not useful to an individual in the absence of an illness or injury; (5) Is appropriate for use in the home.¹⁵

⁵ 42 CFR 405.1006(b)(2).

⁶ See 82 Fed. Reg. 45592 (September 29, 2017).

⁷ 42 CFR 405.1006(d).

⁸ 42 CFR §405.1000(d); A new and independent review not bound by any previous decision(s) issued in a case.

⁹ 42 CFR §400.202; definition of LCD.

¹⁰ 42 CFR §400.202; definition of NCD.

¹¹ 42 CFR §405.1060(a)(4).

¹² 42 CFR §405.1062(a).

¹³ 42 CFR §405.1062(b).

¹⁴ 42 CFR §410.38(a).

¹⁵ 42 CFR 414.202; definition of DME.

Services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member are excluded from Medicare coverage.¹⁶

If the undersigned finds that the durable medical equipment in question was not medically necessary, section 1879 of the Act allows Medicare to make payments for the supplies provided that the beneficiary and the supplier did not know or could not have reasonably known that the items would be excluded.¹⁷ Durable Medical Equipment ("DME") is included under the definition of "medical and other health services."¹⁸ DME is defined as equipment that can stand repeated use; is primarily and customarily used to serve a medical purpose; generally is not useful to an individual in the absence of an illness or injury; and is appropriate for use in the home.¹⁹

In this case, the burden of proving the medical necessity of the supplies in question lies with the Appellant.²⁰ Thus, the Appellant must furnish all information necessary in order to determine if the supplies should be paid by Medicare.²¹

II. Policy

Also considered were the manuals and rulings issued by the Centers for Medicare and Medicaid Services (CMS) in implementing the Medicare program. Specific to the instant case are the following: *CMS, Medicare Claims Processing Manual ("MCPM") (Internet-Only Publ'n: 100-04), Chapter 20, §10.1.1 Durable Medical Equipment; ch. 30, §150 DME Refund Requirements*. For DME and/or supplies to be covered by Medicare, the patient's medical record must contain sufficient documentation substantiating the need for the DME/supplies. A physician's order, certificate of medical necessity ("CMN"), or physician's statement by itself is not sufficient to document medical necessity for the DME/supplies.²²

DME is equipment which: Can withstand repeated use; Is primarily and customarily used to serve a medical purpose; Generally is not useful to a person in the absence of an illness or injury; and, Is appropriate for use in the home. All requirements of the definition must be met before an item can be considered to be durable medical equipment.²³ Items such as hospital beds, wheelchairs, hemodialysis equipment, iron lungs, respirators, intermittent positive pressure breathing machines, medical regulators, oxygen tents, crutches, canes, trapeze bars, walkers, inhalators, nebulizers, commodes, suction machines, and traction equipment presumptively constitute medical equipment.²⁴

Equipment which is primarily and customarily used for a nonmedical purpose may not be considered "medical" equipment for which payment can be made under the medical insurance program. This is true even though the item has some remote medically related use. For example, in the case of a cardiac patient, an air conditioner might possibly be used to lower room temperature to reduce fluid loss in the patient and to restore an environment conducive to maintenance of the proper fluid balance. Nevertheless, because

¹⁶ 42 CFR §411.15(k)(1).

¹⁷ §1879(a)(1)(2); 42 U.S.C. §1395pp(a)(1)(2).

¹⁸ §1861(s)(6); 42 U.S.C. §1395x(s)(6).

¹⁹ 42 C.F.R. § 414.202.

²⁰ 42 C.F.R. § 425.5(a)(6)

²¹ §1833(e); 42 U.S.C. 1395l(e).

²² *MPIM, supra*, ch. 5, §5.7.

²³ *MBPM, supra*, ch. 15, §110.1.

²⁴ *MBPM, supra*, ch. 15, §110.1(B)(1).

the primary and customary use of an air conditioner is a nonmedical one, the air conditioner cannot be deemed to be medical equipment for which payment can be made.²⁵

Although an item may be classified as DME, it may not be covered in every instance. Coverage in a particular case is subject to the requirement that the equipment be necessary and reasonable for treatment of an illness or injury, or to improve the functioning of a malformed body member. These considerations will bar payment for equipment which cannot reasonably be expected to perform a therapeutic function in an individual case or will permit only partial therapeutic function in an individual case or will permit only partial payment when the type of equipment furnished substantially exceeds that required for the treatment of the illness or injury involved.²⁶

Equipment is necessary when it can be expected to make a meaningful contribution to the treatment of the patient's illness or injury or to the improvement of his or her malformed body member. In most cases the physician's prescription for the equipment and other medical information available to the DME will be sufficient to establish that the equipment serves this purpose.²⁷

Even though an item of DME may serve a useful medical purpose, the DME or intermediary must also consider to what extent, if any, it would be reasonable for the Medicare program to pay for the item prescribed. The following considerations should enter into the determination of reasonableness:

1. Would the expense of the item to the program be clearly disproportionate to the therapeutic benefits which could ordinarily be derived from use of the equipment?
2. Is the item substantially more costly than a medically appropriate and realistically feasible alternative pattern of care?
3. Does the item serve essentially the same purpose as equipment already available to the beneficiary?²⁸

Under Medicare policy, payment may be made for supplies, e.g., oxygen, necessary for the effective use of DME.²⁹ Items and services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member are not covered.³⁰

FINDING OF FACTS AND LEGAL ANALYSIS

This case is before the undersigned Administrative Law Judge ("ALJ") under *de novo* review of whether Appellant is entitled to payment for Optune (also referred to as Optune Tumor Treating Fields Therapy/TTFT), a portable medical device that delivers alternating electric fields or tumor treating fields to the brain. Appellant requested pre-approval for Optune for dated of service March 7, 2018 through June, 2018, which the Plan denied on the grounds that the device and treatment thereof was not medically necessary according to the guidelines of LCD, L34823.

²⁵ MBPM, *supra*, ch. 15, §110.1(B)(2)).

²⁶ MBPM, *supra*, ch. 15, §110.1(C).

²⁷ MBPM, *supra*, ch. 15, §110.1(C)(1)).

²⁸ MBPM, *supra*, ch. §110.1(C)(2)

²⁹ MBPM, *supra*, ch. 15, 110.3.

³⁰ MBPM, *supra*, ch. 16, §20.

Pursuant to 42 C.F.R. §405.1062 of the Medicare regulations, an ALJ is not bound by LCDs, LMRPs, or CMS program guidance, but must give them “substantial deference” when applicable, or must explain why he has deviated from them. The undersigned has determined the facts and circumstances of this warrant deviation from the guiding LCD, and shall approve approval of the device for the following reasons:

The device is classified as DME and meets all relevant definitions of durable medic equipment set forth in the above-mentioned Medicare policy. Effective January 1, 2014, CMS classified Optune as DME requiring frequent and substantial servicing, meaning the device, supplies and service are all bundled under one HCPCS code, E0766. Optune is FDA-approved for both recurrent and newly diagnosed glioblastoma multiforme (“GBM”) brain tumors. Appellant was clinically diagnosed with GBM following a brain MRI on November 18, 2017, which verified presence of a large mass in the right superior frontal gyrus of his brain. The same month Appellant underwent a craniotomy and gross total resection, with pathology confirmation of “biologically aggressive” GBM.³¹

Appellant was initially treated with radiation therapy in December of 2017, and scheduled to start chemotherapy with Temodar concurrently followed TTFT as prescribed by his oncology, Dr. Amit Sanyal, M.D.³² This treatment regimen is within the accepted standard of care for GBM. However, due to “insurance reasons” Appellant was only treated with radiation therapy until the last week, which he finished on January 16, 2018, and was scheduled to begin Optune therapy around March 6, 2018 or March 12, 2018. According to sworn medical testimony at the hearing, Appellant’s treatment was interrupted when he developed deep vein thrombosis and subsequently started on anticoagulation therapy on January 11, 2018. Despite the radiation and chemotherapy treatment, a follow-up MRI of the brain on February 14, 2018, revealed disease progression and a new nodule mass. Appellant began the second cycle of Temodar on March 18, 2018, but another MRI showed worsening of the enhancing mass on April 4, 2018, reflecting the aggressiveness of this form of cancer.

On April 16, 2018, Appellant underwent the third cycle of Temodar, and had developed steroid toxicity, which the treating physician ordered tapered down. Temodar treatment was discontinued on May 10, 2018, because Appellant developed an onset of thrombocytopenia. During this time, Appellant was only under Optune treatment based on his poor clinical status as determined by his treating physicians. Appellant was continued on Optune therapy as the TTFT treatment was believed to be helping him, and given that the other treatment options were not appropriate or available (because of his medical condition). Following continued Optune treatment, Appellant had not developed any new neurological symptoms, focal deficits, or seizures as of June 25, 2018. Novocure was subsequently informed the Appellant had stopped using Optune TTFT on July 5, 2018.

The nature of Appellant’s brain cancer in this case was particularly aggressive and unresponsive to alternative treatment regimens. The aforementioned facts and circumstances support the medical necessity of the DME at issue, in the treatment of Appellant’s medical condition. Use of the DME in this case was a life-saving, or at the least life-prolonging measure for Appellant. Thus, for the above reasons, deviation from the guiding LCD is warranted and approval of the DME (and treatment therewith) as billed under E0766 is hereby approved.

³¹ Exhibit 2, pages 4-10.

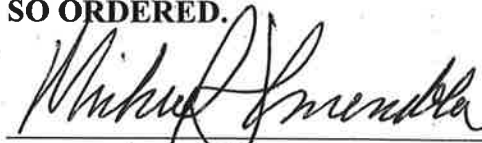
³² Exhibit 2, page 3.

Conclusions of Law

For the above-mentioned reasons, Appellant's request for Medicare coverage of Optune TTFT is approved. The DME has been proven to be medically necessary in the treatment of Appellant's aggressive brain cancer based upon a preponderance of the evidence and sworn hearing testimony provided at the ALJ hearing.

ORDER

The Medicare contractor provider is directed to pay Appellant's claim in accordance with this decision.

SO ORDERED.

Michael Amendola
U.S. Administrative Law Judge

Dated: OCT 24 2018



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Miami, Florida

Appeal of: F. STOHL	OMHA Appeal No.: 1-7538272290
Enrollee: F. STOHL	Medicare: Part C
HICN: *****6880A	Before: Michael Amendola Administrative Law Judge

EXHIBIT LIST

EXHIBIT NUMBER	DESCRIPTION	PAGE NUMBERS
1	Organization Determination, MAO Reconsideration and Part C QIC Reconsidered Decision Procedural Documents/EOC	291
2	Medical Records/Evidence received by MAO and CMS contractors	31
3	Request for ALJ Hearing	1
4	OMHA Proceedings	

Dated:

REQUEST FOR REVIEW OF ADMINISTRATIVE LAW JUDGE (ALJ) MEDICARE DECISION / DISMISSAL

1. APPELLANT (the party requesting review)	2. ALJ APPEAL NUMBER (on the decision or dismissal)
3. BENEFICIARY*	4. HEALTH INSURANCE CLAIM NUMBER (HICN)*

*If the request involves multiple claims or multiple beneficiaries, attach a list of beneficiaries, HICNs, or other information to identify all claims being appealed.

5. PROVIDER, PRACTITIONER, OR SUPPLIER	6. SPECIFIC ITEM(S) OR SERVICE(S)
7. Medicare claim type: <input type="checkbox"/> Part A <input type="checkbox"/> Part B <input type="checkbox"/> Part C - Medicare Advantage <input type="checkbox"/> Part D - Medicare Prescription Drug Plan <input type="checkbox"/> Entitlement/enrollment for Part A or Part B	
8. Does this request involve authorization for an item or service that has not yet been furnished? <input type="checkbox"/> Yes If Yes, skip to Block 8. <input type="checkbox"/> No If No, Specific Dates of Service:	

9. If the request involves authorization for a prescription drug under Medicare Part D, would application of the standard appellate timeframe seriously jeopardize the beneficiary's life, health, or ability to regain maximum function (as documented by a physician) such that expedited review is appropriate? ☐ Yes ☐ No

I request that the Medicare Appeals Council review the ALJ's ☐ decision or ☐ dismissal order [check one] dated _____. I disagree with the ALJ's action because (specify the parts of the ALJ's decision or dismissal you disagree with and why you think the ALJ was wrong):

(Attach additional sheets if you need more space)

PLEASE ATTACH A COPY OF THE ALJ DECISION OR DISMISSAL ORDER YOU ARE APPEALING.

DATE			DATE		
APPELLANT'S SIGNATURE (the party requesting review)			REPRESENTATIVE'S SIGNATURE (include signed appointment if not already submitted.)		
PRINT NAME			PRINT NAME		
ADDRESS			ADDRESS		
CITY, STATE, ZIP CODE			CITY, STATE, ZIP CODE		
TELEPHONE NUMBER	FAX NUMBER	E-MAIL	TELEPHONE NUMBER	FAX NUMBER	E-MAIL

(SEE FURTHER INSTRUCTIONS ON PAGE 2)

If you have additional evidence, submit it with this request for review. If you need more time, you must request an extension of time in writing now, explaining why you are unable to submit the evidence or legal argument now.

If you are a provider, supplier, or a beneficiary represented by a provider or supplier, and your case was reconsidered by a Qualified Independent Contractor (QIC), the Medicare Appeals Council will not consider new evidence related to issues the QIC has already considered unless you show that you have a good reason for submitting it for the first time to the Medicare Appeals Council.

IMPORTANT: Include the HICN and ALJ Appeal Number on any letter or other material you submit.

This request must be received within 60 calendar days after you receive the ALJ's decision or dismissal, unless we extend the time limit for good cause. We assume you received the decision or dismissal 5 calendar days after it was issued, unless you show you received it later. If this request will not be received within 65 calendar days from the date on the decision or dismissal order, please explain why on a separate sheet.

You must file your request for review in writing with the Medicare Appeals Council at:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

You may send the request for review by U.S. Mail, a common carrier such as FedEx, or by fax to (202) 565-0227. If you send a fax, please do not also mail a copy. **You must send a copy of your appeal to the other parties and indicate that all parties, to include all beneficiaries, have been copied on the request for review. For claims involving multiple beneficiaries, you may submit a copy of the cover letters issued or a spreadsheet of the beneficiaries and addresses who received a copy of the request for review.**

If you have any questions about your request for review or wish to request expedited review of a claim involving authorization of your prescription drug under Medicare Part D, you may call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100. You may also visit our web site at www.hhs.gov/dab for additional information on how to file your request for review.

PRIVACY ACT STATEMENT

The collection of information on this form is authorized by the Social Security Act (section 205(a) of title II, section 702 of title VII, section 1155 of Title XI, and sections 1852(g)(5), 1869(b)(1), 1871, 1872, and 1876(c)(5)(B) of title XVIII, as appropriate). The information provided will be used to further document your claim. Information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your claim. Information you furnish on this form may be disclosed by the Department of Health and Human Services or the Social Security Administration to another person or governmental agency only with respect to programs under the Social Security Act and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services, the Social Security Administration, or other agencies.



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Irvine, California

Appeal of:	OMHA Appeal No.: 1-8248014949
Enrollee:	Medicare: Part C
Medicare No.: *****7200A	Before: Dean R. Yanohira Administrative Law Judge

DECISION

After careful consideration of all the evidence and arguments presented in the record and at the hearing, a **FULLY FAVORABLE** decision is entered in this matter.

Procedural History

The Appellant/Enrollee is a Medicare beneficiary enrolled in HumanaChoice, a Medicare Advantage ("MA") organization, sponsored by Humana Insurance Company ("Humana" or "Plan"). The Appellant/Enrollee submitted a request for prior authorization for coverage of tumor treatment field therapy ("TTFT" or electric stimulator device for cancer treatment) (E0766) from the Supplier Novocure, Inc. On initial determination and redetermination, the Plan denied coverage. The Appellant/Enrollee requested a reconsideration review by MAXIMUS Federal Services, the Independent Review Entity ("IRE") with jurisdiction. On January 11, 2019, the IRE issued an unfavorable decision and upheld the denial. (See Exh. 1).

On January 25, 2019, the Office of Medicare Hearings and Appeals ("OMHA") received the Appellant's timely filed Request for Hearing before an Administrative Law Judge ("ALJ"). (Exh. 3). The amount in controversy met the jurisdictional requirement. (Exh. 1). The appeal file includes an Appointment of Representative form designating Debra M. Parrish as the Appellant/Enrollee's appointed representative. (Exh. 5).

Pursuant to a written notice, the undersigned ALJ held a telephone hearing in Irvine, California on March 11, 2019. Debra M. Parrish, Esq., the Appellant/Enrollee's appointed representative appeared. Julie Miles, R.N. with Optune appeared as a witness. Marcia Taylor and Bryan Carr, M.D. with Humana appeared for the Plan. The IRE did not respond to the notice of hearing. All exhibits described in the Exhibit List were admitted into the record without objection. (See Hearing CD).

Issue

Whether the Appellant/Enrollee's MA Plan is required to pre-approve coverage of tumor treatment field therapy (E0766) pursuant to Section 1862(a)(1) of the Social Security Act ("Act") and implementing regulations and guidelines?

Findings of Fact

The Appellant/Enrollee is a member of HumanaChoice, a Medicare Advantage ("MA") organization, sponsored by Humana Insurance Company ("Humana" or "Plan"). (See Exh. 1).

A brain MRI report on December 28, 2017 indicates that the Appellant/Enrollee had postoperative changes with decrease pneumocephalus and increased fluid along the frontal convexity and in the resection cavity. (Exh. 2, pp. 5-7).

A brain MRI report on March 22, 2018 indicates that the Appellant/Enrollee had a history of glioblastoma multiforme status post total or near-total resection. The impression from the report shows that the increased perfusion, nodular enhancement, and focal diffusion restriction in the posterior superior margin of the resection cavity is concerning for residual of recurrent neoplasm. (Exh. 2, pp. 3-4).

A brain MRI report on May 3, 2018 indicates that the imaging findings are most concerning for interval progression of tumor even in the clinical setting of having recently completed radiation therapy. Also, the small extra-axial fluid collection was unchanged. (Exh. 2, pp. 32-33).

Progress notes on May 3, 2018 indicate that the Appellant/Enrollee was a 75-year-old female who was diagnosed with glioblastoma multiforme of the brain. Her treatment history included gross total resection on December 4, 2017; Temozolomide and XRT from January 18 to February 26, 2018; and Temozolomide and Optune/TTF (tumor treatment field) therapy in April 2018. There is evidence of disease progression on the imaging. The Appellant/Enrollee is very early in her therapy in the adjuvant setting, and it is very concerning. The physician reviewed options, including use of Bevacizumab, which would be appropriate for either progressive tumor or radiation-necrosis. The question is really whether or not her current therapy (adjuvant temozolomide and TTF) has had sufficient treatment time to assess if it is progressive. (Exh. 2, pp. 22-25).

Progress notes on May 21, 2018 indicate that the Appellant/Enrollee was diagnosed with right frontal glioblastoma multiforme, and on that day, her treatment included Bevacizumab – Temozolomide – TTF therapy. (Exh. 2, pp. 14-16).

Progress notes on June 14, 2018 indicate that the Appellant/Enrollee received Bevacizumab – Temozolomide – TTF therapy on May 21, 2018. She tolerated cycle one well. She had no thrombotic or bleeding issues, and her blood pressure is under good control. She noted no symptoms referable to the Bevacizumab. She is getting stronger and noting balance improvement with her physical therapy. Her main residual concern is fatigue, and the plan was to increase the dose of Methylphenidate. (Exh. 2, pp. 17-21).

Progress notes on July 5, 2018 indicate that the Appellant/Enrollee had resection surgery on December 4, 2017. She has been clinically doing well on the combination of Temozolomide/Bevacizumab and TTF (tumor treatment field) therapy. There are no adverse events with the Bevacizumab, and the blood pressure is under good control. The plan was to have an MRI in six weeks. (Exh. 2, pp. 9–12).

A brain MRI report on August 20, 2018 indicates that there has been interval reduction of the confluent T2/Flair signal in the right frontal lobe, compatible with decreased surrounding vasogenic edema. (Exh. 2, pp. 37–38).

Progress notes on August 20, 2018 indicate that the Appellant/Enrollee was assessed with glioblastoma multiforme. Clinically, she was doing well. She had no new neurological deficits, and if anything, they are improving. (Exh. 2, pp. 42–46).

The Optune Prescription Form, dated September 17, 2018, indicates that the Appellant/Enrollee was diagnosed with glioblastoma multiforme (ICD-10 code C71.9). This was a renewal prescription for the use of Optune for 6 months. (Exh. 2, p. 1).

Optune, formerly known as NovoTTF-100A System, has been approved by the United States (U.S.) Food and Drug Administration (FDA) to deliver TTFT therapy. TTFT therapy is delivered by is a portable battery or power supply operated device, which produces alternating electrical fields, called tumor treatment fields ("TTFields") within the human body. TTFields are applied to the patient by electrically-insulated surface electrodes. The TTFields are used to disrupt the rapid cell division exhibited by cancer cells. The NovoTTF-100A System is comprised of two main components: (1) an Electric Field Generator (the NovoTTF-100A device); and (2) INE Insulated Electrodes (the electrodes).¹

The Appellant submitted an article from JAMA (Journal of American Medical Association) entitled, *"Influence of Treatment With Tumor-Treating Fields on Health-Related Quality of Life of Patients With Newly Diagnosed Glioblastoma"* in support of its position. This was a second analysis of a randomized clinical trial. The study included 695 patients with glioblastoma after completion of radiochemotherapy. The study found that the addition of TTFields to standard treatment with temozolomide for patients with glioblastoma results in improved survival without a negative influence, except for more itchy skin, an expected consequence from the transducer arrays. The study concluded that use of TTFields prolongs progression-free and overall survival in patients with glioblastoma. (Exh. 5, pp. 14–22).

The Appellant submitted an article from JAMA entitled, *"Effect of Tumor-Treating Fields Plus Maintenance Temozolomide vs Temozolomide Alone on Survival in Patients with Glioblastoma"* in support of its position. The study involved a randomized clinical trial of 695 patients with glioblastoma whose tumor was resected or biopsied and had completed concomitant radiochemotherapy. The study found that the addition of TTFields to maintenance temozolomide chemotherapy vs. maintenance therapy alone resulted in statistically significant improvement in progression-free survival and overall survival. (Exh. 5, pp. 23–33).

¹ https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034c.pdf

According to the FDA website, “the *breakthrough* finding made by NovoCure was that finely tuned alternating fields of very low intensity, now termed TTFields (Tumor Treating Fields) cause a significant slowing in the growth of cancer cells. Due to the unique geometric shape of cancer cells when they are multiplying, TTFields cause the building blocks of these cells to move and pile up in such a way that the cells physically explode. In addition, cancer cells also contain miniature building blocks which act as tiny motors in moving essential parts of the cells from place to place. TTFields cause these tiny motors to fall apart since they have a special type of electric charge. As a result of these two effects, cancer tumor growth is slowed and can even reverse after continuous exposure to TTFields. Other cells in the body (normal healthy tissues) are affected much less than cancer cells since they multiply at a much slower rate if at all. In addition, TTFields can be directed to a certain part of the body, leaving sensitive areas out of their reach. In conclusion, TTFields hold the promise of serving as a brand new cancer treatment with very few side effects and promising affectivity in slowing or *reversing* this disease.”²

Legal Framework

I. ALJ Review Authority

A. *Jurisdiction*

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. (Section 1869(b)(1)(A) of the Social Security Act (“Act”).

In implementing this statutory directive, the Secretary has delegated her authority to administer the nationwide hearings and appeals systems for the Medicare program to OMHA. (70 Federal Register 36386, 36387 (June 23, 2005)). The Administrative Law Judges (“ALJs”) within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. (*Id.*).

With respect to the dates of service at issue, a request for ALJ hearing meets the amount in controversy requirement if it comports with 42 C.F.R. § 405.1006(b) (1). A request for ALJ hearing is timely filed if filed within 60 days after receipt of the notice of the Qualified Independent Contractor (“QIC”) decision. (42 C.F.R. § 405.1002).

B. *Scope of Review*

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the Appellant's favor. However, if evidence presented before or during the hearing causes the ALJ to question a favorable portion of the determination, he or she may notify the parties before the hearing and may consider it an issue at the hearing. (42 C.F.R. § 405.1032(a)).

² https://clinicaltrials.gov/ct2/show/study/NCT00916409?show_desc=Y#desc

C. *Standard of Review*

According to 42 C.F.R. § 405.1000(d), the ALJ conducts a *de novo* review and issues a decision based on the hearing record.

II. Principles of Law

A. *Statutes and Regulations*

Eligibility for Medicare benefits is determined under Title XVIII of the Social Security Act, 42 U.S.C. §1801 et seq., and federal regulations set forth in Title 42 of the Code of Federal Regulations.

The obligations of a Medicare Advantage (“MA”) organization to its enrollees are set forth in Section 1852 of the Social Security Act and the implementing regulations in 42 C.F.R. Part 422.

Pursuant to 42 C.F.R. § 422.101, except as specified in §422.318 (for entitlement that begins or ends during a hospital stay) and §422.320 (with respect to hospice care), each Medicare Advantage (“MA”) organization must provide coverage of all services that are covered by Part A and Part B of Medicare and that are available to enrollees residing in the plan’s service area. Services may be provided outside of the service area of the plan if the services are accessible and available to enrollees.

The Medicare Part B program entitles a beneficiary to have payment made to him or her on his or her behalf for medical and other health services. (Act § 1832(a)(1); *see also* 42 C.F.R. § 410.3(a)(1)). Coverage of medical and other health services is qualified by the overarching principles of sections 1862(a) and 1833(e) of the Act.

Section 1833(e) of the Social Security Act states that no payment shall be made to any provider of service unless supported by sufficient information. (*See also* 42 C.F.R. § 424.5(a)(6)).

Section 1862(a)(1) of the Social Security Act excludes from Medicare coverage and payment, items and services which are not medically reasonable and necessary for the diagnosis and treatment of an illness or injury, or to improve the functioning of a malformed body member. Additionally, section 1862(a)(9) of the Act excludes from Medicare coverage expenses related to custodial care. (*See also* 42 C.F.R. § 411.15(k)(1)).

Section 1879 of the Social Security Act provides that when Medicare excludes payment and coverage pursuant to Section 1862(a)(1) of the Social Security Act, payment may nevertheless be made for the items or services, if neither the beneficiary nor the provider or supplier knew, and could not reasonably be expected to have known, that the items or services would not be covered or payable by Medicare. (*See also* 42 C.F.R. § 411.406).

According to 42 C.F.R. § 422.562(d)(1), unless otherwise specified, unless this subpart provides otherwise and subject to paragraph (d)(2) of this section, the regulations in part 405 of this chapter (concerning the administrative review and hearing processes and representation of parties under titles II and XVIII of the Act) apply under this subpart to the extent they are appropriate.

Under 42 C.F.R. § 422.562(d)(2), the following regulations in part 405 of this chapter, and any references thereto, specifically do not apply under this subpart: (i) Section 405.950 (time frames for making a redetermination); (ii) Section 405.970 (time frames for making a reconsideration following a contractor redetermination, including the option to escalate an appeal to the OMHA level); (iii) Section 405.1016 (time frames for deciding an appeal of a QIC reconsideration, or escalated request for a QIC reconsideration, including the option to escalate an appeal to the Council); (iv) The option to request that an appeal be escalated from the OMHA level to the Council as provided in §405.1100(b), and time frames for the Council to decide an appeal of an ALJ's or attorney adjudicator's decision or an appeal that is escalated from the OMHA level to the Council as provided in §405.1100(c) and (d); (v) Section 405.1132 (request for escalation to Federal court); and (vi) Sections 405.956(b)(8), 405.966(a)(2), 405.976(b)(5)(ii), 405.1018(c), 405.1028(a), and 405.1122(c), and any other reference to requiring a determination of good cause for the introduction of new evidence by a provider, supplier, or a beneficiary represented by a provider or supplier.

42 C.F.R. § 405.1062(a) provides that ALJs and attorney adjudicators and the Council are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.

42 C.F.R. § 405.1062(b) states that if an ALJ or attorney adjudicator or Council declines to follow a policy in a particular case, the ALJ or attorney adjudicator or Council decision must explain the reasons why the policy was not followed. An ALJ or attorney adjudicator or Council decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.

42 C.F.R. § 405.1062(c) provides that an ALJ or attorney adjudicator or the Council may not set aside or review the validity of an LMRP or LCD for purposes of a claim appeal. An ALJ or the DAB may review or set aside an LCD (or any part of an LMRP that constitutes an LCD) in accordance with part 426 of this title.

B. Policy and Guidance

Section 1871(a)(2) of the Social Security Act provides that, unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than a National Coverage Determination ("NCD"), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and Local Medical Review Policies ("LMRPs") or Local Coverage Determinations ("LCDs"). These policies are not binding on an Administrative Law Judge in adjudicating a claim, but the regulations require that the policies be afforded "substantial deference" and any departure therefrom be explained in the resulting decision. (See 42 C.F.R. § 405.1062).

The Medicare Contractor issued LCD L34823 for Tumor Treatment Field Therapy (TTFT) (Revision Effective Date Jan. 1, 2017). It provides, in part, the following:

Coverage Indications, Limitations, and/or Medical Necessity

....
The purpose of a Local Coverage Determination (LCD) is to provide information regarding “reasonable and necessary” criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the “reasonable and necessary” criteria contained in this LCD there are other payment rules, which are discussed in the following documents that must also be met prior to Medicare reimbursement:

For the items addressed in this LCD, the “reasonable and necessary” criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

HCPCS Codes

....
E0766 ELECTRICAL STIMULATION DEVICE USED FOR CANCER TREATMENT, INCLUDES ALL ACCESSORIES, ANY TYPE
....

The related Policy Article A52711 for Tumor Treatment Field Therapy (TTFT) (Revision Effective Date Jan. 1, 2017) provides, in part, the following:

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

Information provided in this policy article relates to determinations other than those based on Social Security Act § 1862(a)(1)(A) provisions (i.e. “reasonable and necessary”). Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act § 1861(s)(6)). In order for a beneficiary’s equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Code E0766 is in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories.

Separate billing of supplies and/or accessories will be denied as unbundling. Code A4555 is not valid for billing to Medicare. If code A4555 is billed, it will be denied as an invalid code.

CODING GUIDELINES

Code E0766 describes devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers.

This code is inclusive of all associated supplies necessary for the effective use of code E0766 including, but not limited to, transducers/surface electrodes, lead wires, adhesive patches, connectors, conductive gel and skin preps.

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Central Nervous System Cancers Version 1.2018 provides that alternating electric field therapy for glioblastoma and is a category 2A recommendation.

Analysis

At issue is whether the Appellant/Enrollee's MA Plan is required to pre-approve coverage of tumor treatment field therapy ("TTFT" or electrical stimulation device for cancer treatment) (E0766) pursuant to Section 1862(a)(1) of the Social Security Act ("Act") and implementing regulations and guidelines.

Pursuant to 42 C.F.R. § 422.101, except as specified in §422.318 (for entitlement that begins or ends during a hospital stay) and §422.320 (with respect to hospice care), each Medicare Advantage ("MA") organization must provide coverage of all services that are covered by Part A and Part B of Medicare and that are available to enrollees residing in the plan's service area.

Medicare makes payment on items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." (See § 1862(a)(1) of the Act). All Medicare claims for payment must be supported by sufficient information and documentation. (See § 1833(e) of the Act).

The MA Plan indicated in its Notice of Denial of Medical Coverage, dated November 28, 2018, that according to LCD L34823 and related Policy Article A52711, tumor treatment field therapy (E0766) is not reasonable and necessary. (Exh. 1, pp. 34-36).

The IRE in its reconsideration stated that tumor treatment field therapy is denied as not reasonable and necessary according to the applicable LCD. (Exh. 1, pp. 1-4).

The Medicare Administrative Contractor has published guidelines addressing the indications and limitations of coverage for TTFT. These guidelines are contained in Local Coverage Determination (“LCD”) L34823 and Policy Article A52711. An LCD is program guidance developed by a Medicare contractor and is applicable only in that contractor’s service area. An ALJ is not bound by program guidance such as LCDs, program memoranda or manual instructions. However, an ALJ must give such policies substantial deference if applicable in a particular case. (42 C.F.R. § 405.1062(a)). If an ALJ declines to follow a policy in a particular case, the rationale for not following that policy must be explained. (42 C.F.R. § 405.1062(b)).

According to LCD L34823, tumor treatment field therapy (“TTFT”), including electrical stimulation device used for cancer treatment (E0766), will be denied as not reasonable and necessary. The related Policy Article A52711 provides that that TTFT are not covered under the Durable Medical Equipment (“DME”) benefit. It also states that Code E0766 describes devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers. This code is inclusive of all associated supplies necessary for the effective use of code E0766 including, but not limited to, transducers/surface electrodes, lead wires, adhesive patches, connectors, conductive gel and skin preps.

The undersigned ALJ notes that there is a Medicare Appeals Council (“Council”) decision opining that it not appropriate to apply the substantial deference provisions of 42 C.F.R. § 405.1062(a) and (b), which permit an ALJ to depart from an LCD, in Medicare Part C. The undersigned ALJ respectfully disagrees with the rationale that LCDs are binding on ALJs for issues involving MA plans but not on issues involving original Medicare. According to 42 C.F.R. § 422.562(d), unless otherwise specified, the regulations in part 405 apply to Part C cases. There is no mention of 42 C.F.R. § 405.1062 not applying in Medicare Part C. Moreover, 42 C.F.R. § 422.101(a) states that an MA organization must provide coverage for all services that would be covered under Original Medicare Part B. If an ALJ decides to depart from an LCD under original Medicare Part B and cover an item/service, but is not allowed to depart from an LCD in Medicare Part C, this same item/service would be covered under Part B but not allowed under Part C. Therefore, TTFT could be allowed under Medicare Part B but never allowed under Medicare Part C. Applying that rationale would cause inconsistent results within the Medicare program, which is not the intent of the Medicare program based on the language of the applicable regulations.

At the hearing, the Plan’s medical director acknowledged that the Plan allows coverage for TTFT for commercial members, but does not allow coverage for TTFT under Medicare Part C because of the applicable LCD. This fact, along with the submitted medical literature, supports the medical necessity of TTFT. If the Plan covers TTFT for its commercial members because it believes that TTFT is helpful in slowing down the progression of glioblastoma, but is denying coverage only because it is directed by the applicable LCD, the undersigned ALJ finds further support to depart from the applicable LCD.

The undersigned ALJ declines to follow LCD L34823 for the foregoing reasons. TTFT has been approved by the Food and Drug Administration (FDA)³. According to the FDA website, “the

³The U.S. Food and Drug Administration, in October 2015, approved an expanded indication for the Optune device by NovoCure for TTF (the treatment at issue in this appeal), to treat patients, as the Appellant, with newly-diagnosed GBM. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm465744.htm>.

breakthrough finding made by NovoCure was that finely tuned alternating fields of very low intensity, now termed TTFields (Tumor Treating Fields), cause a significant slowing in the growth of cancer cells. Due to the unique geometric shape of cancer cells when they are multiplying, TTFields cause the building blocks of these cells to move and pile up in such a way that the cells physically explode. In addition, cancer cells also contain miniature building blocks which act as tiny motors in moving essential parts of the cells from place to place. TTFields cause these tiny motors to fall apart since they have a special type of electric charge. As a result of these two effects, cancer tumor growth is slowed and can even reverse after continuous exposure to TTFields. Other cells in the body (normal healthy tissues) are affected much less than cancer cells since they multiply at a much slower rate if at all. In addition, TTFields can be directed to a certain part of the body, leaving sensitive areas out of their reach. In conclusion, TTFields hold the promise of serving as a brand new cancer treatment with very few side effects and promising affectivity in slowing or reversing this disease.”⁴ The FDA asserts that cancer growth is slowed and can be reversed after using this device. Also, as discussed in the Findings of Facts section, the Appellant/Beneficiary has provided multiple examples of literature accepted by medical oncology professionals that support successful trials of the Optune stimulator for treatment of glioblastoma.

The documentation submitted includes clinical records indicating that the Appellant/Enrollee was a 75-year-old female who was diagnosed with glioblastoma multiforme of the brain. She underwent gross total resection on December 4, 2017. A brain MRI report on December 28, 2017 indicates that she had postoperative changes with decrease pneumocephalus and increased fluid along the frontal convexity and in the resection cavity. A brain MRI report on March 22, 2018 shows that the increased perfusion, nodular enhancement, and focal diffusion restriction in the posterior superior margin of the resection cavity is concerning for residual of recurrent neoplasm. In addition to surgery, the Appellant/Enrollee’s treatment history included Temozolomide and XRT from January 18 to February 26, 2018, and Temozolomide and Optune/TTF therapy in April 2018. A brain MRI report on May 3, 2018 indicates that the imaging findings are most concerning for interval progression of tumor even in the clinical setting of having recently completed radiation therapy, and the small extra-axial fluid collection was unchanged. Progress notes on May 3, 2018 indicate that there is evidence of disease progression on the imaging. The notes state that the Appellant/Enrollee was very early in her therapy in the adjuvant setting, and it is very concerning. The physician reviewed options, including use of Bevacizumab, which would be appropriate for either progressive tumor or radiation necrosis. The question is really whether or not her current therapy (adjuvant temozolomide and TTF) has had sufficient treatment time to assess if is progressive. Progress notes on May 21, 2018 indicate that the Appellant/Enrollee began treatment with Bevacizumab – Temozolomide – TTF therapy. Progress notes on June 14, 2018 state that the Appellant/Enrollee received Bevacizumab – Temozolomide – TTF therapy on May 21, 2018, and she tolerated cycle one well; she had no thrombotic or bleeding issues; her blood pressure is under good control; she noted no symptoms referable to the Bevacizumab; and she was getting stronger. Progress notes on July 5, 2018 indicate that the Appellant/Enrollee has been clinically doing well on the combination of Temozolomide/Bevacizumab and TTF (tumor treatment field) therapy; there are no adverse events with the Bevacizumab; and her blood pressure is under good control. A brain MRI report on August 20, 2018 indicates that there has been interval reduction of the confluent T2/Flair signal in the right frontal lobe, compatible with decreased surrounding vasogenic

⁴ https://clinicaltrials.gov/ct2/show/study/NCT00916409?show_desc=Y#desc

edema. Progress notes on August 20, 2018 indicate that the Appellant/Enrollee was clinically doing well; she had no new neurological deficits, and if anything, they are improving. Based on the clinical records submitted, the Appellant/Enrollee's severe condition required treatment of TTFT, and she responded very well to the treatment. Thus, the evidence supports a finding that the device at issue is medically reasonable and necessary for treatment of the Appellant/Enrollee's condition.

While giving consideration to the requisite LCD, the undersigned ALJ finds that this LCD cannot be followed in this case for a multitude of reasons. The LCD states that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. Nevertheless, the IRE based its decision on an LCD that does not contain any discussion, rationale, or any explanation for its conclusions. LCD L34823 generally denies that *any* TTFT treatment is reasonable and necessary under *any* circumstance without setting forth an underlying basis, discussion, criteria, or rationale for that determination. LCD L34823 is noticeably outdated and ignores medically relevant data and research findings that are accepted in the medical oncology industry, and it ignores the recent medical findings of the FDA. This data and research, which has been ignored, supports a finding that TTFT treatment is medically reasonable and necessary for patients like the Appellant/Beneficiary. TTFT is not experimental or investigational but has been approved by the FDA. Furthermore, the sparse nature of any medical reasoning in LCD L34823 provides additional reasons not to follow it here, where the medical evidence, testimony, and argument strongly support the Appellant/Enrollee's case. Regardless of the guidance provided by LCD L34823, a departure from the guidelines set forth in this LCD is justified based upon the Appellant/Enrollee's serious condition, the great benefits received by the Appellant/Enrollee after using this device, and the medical findings and research that are accepted among medical oncology professionals. Furthermore, federal regulations *permit* ALJs to decline to follow a local coverage policy. (See 42 C.F.R. § 405.1062(b)). As discussed above, the undersigned ALJ disagrees with the rationale that LCDs are binding on ALJs on issues involving MA plans, but not on issues involving original Medicare, which provides inconsistent results within the Medicare program.

Based on the totality of the evidence of record, as discussed above, the undersigned ALJ finds that the TTFT (E0766) at issue was medically reasonable and necessary and is covered under Medicare rules and guidelines. As such, the MA Plan is required to pre-approve coverage of TTFT for the Appellant/Enrollee.

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Conclusions of Law

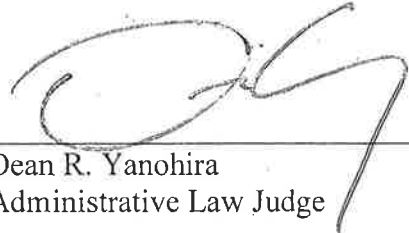
The undersigned ALJ concludes that the Appellant/Enrollee's MA Plan is required to pre-approve coverage of tumor treatment field therapy (E0766) pursuant to Section 1862(a)(1) of the Social Security Act ("Act") and implementing regulations and guidelines.

ORDER

The Medicare Advantage Plan is directed to process the claim in accordance with this decision.

SO ORDERED

Dated: **MAR 14 2019**



Dean R. Yanohira
Administrative Law Judge



**Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Arlington, Virginia**

Appellant:

ALJ Appeal No.: **1-7585537269**

Enrollee:

Medicare: **Part C**HICN: *******7200A**Before: **Scott Anderson
Administrative Law Judge**

DECISION

After carefully considering the evidence in the record and arguments presented at the hearing, I enter a **FULLY FAVORABLE** decision for the Appellant/Enrollee (Appellant) in this matter.

PROCEDURAL HISTORY

Appellant is enrolled in HumanaChoice a Medicare Advantage Plan administered by Humana (hereinafter Humana or the Plan). Appellant submitted a claim to the Plan for pre-approval of an electrical stimulation device used for cancer treatment (HCPCS E0766) to be provided by the Provider, Novocure, Inc. (also known as Optune) from March 30, 2018 to September 30, 2018. On April 10, 2018, Humana denied the request because:

Your condition did not meet the Medicare rule for approval of a device used for cancer treatment (electrical stimulation device used for cancer treatment includes all accessories, any type). Your records show you have brain cancer (malignant neoplasm of brain). The Medicare rule says tumor treatment field therapy will be denied as not reasonable and necessary. Under Medicare rules your request is not medically necessary.

Ex. 1 at 24.

In a May 7, 2018 letter, treating oncologist Sara Grethlein, M.D., requested redetermination on Appellant's behalf. Ex. 1 at 33-34. The requested stated:

[Appellant] sought medical treatment and was found to have a right frontal brain mass. She underwent a gross total resection on December 4, 2017 which was followed by courses of radiation and Temozolomide. As of March 22, 2018 her neurological deficits have all resolved, however, post-operative MRI on the same date was documented as concerning for recurrent neoplasm. Suspicion is so high that [Appellant] was planned for a follow-up MRI at a one month interval as opposed to a 2 month interval.

After discussing treatment options with [Appellant], I have decided to prescribe Optune in combination with [T]emozolomide as this currently is the best option for treating her glioblastoma.

Alternative electric field therapy (Optune) + adjuvant temozolomide is now an NCCN Category 2A recommendation following postoperative standard brain radiation therapy with concurrent [T]emozolomide.

...
Optune received pre-market approval from the FDA for recurrent glioblastoma in April 2011. This approval was based on the results of a large randomized controlled trial of patients with recurrent GBM comparing Optune as a monotherapy to standard chemotherapy use in recurrent GBM. The results showed that treatment with Optune delivered comparable overall survival and progression free survival to chemotherapy with minimal toxicity and an improvement in patients quality of life compared to chemotherapy.

In 2015, Optune received pre-marketing approval from the FDA for newly diagnosed glioblastoma in combination with [T]emozolomide after standard surgical resection and radiation therapy.

...
It is my belief that Optune in combination with [T]emozolomide is the most appropriate option for [Appellant] at the present time.

Ex. 1 at 33-34 (emphasis in original).

In response, Humana upheld the initial determination, stating that: “Local Coverage Determination (LCD) for Tumor Treatment Field Therapy (TTFT) (L34823) for Indiana, which states, ‘T field therapy (E0766) will be denied as not reasonable and necessary.’” Ex. 1 at 15.

Appellant requested reconsideration from Maximus Federal Services (MAXIMUS), a Medicare Independent Review Entity (IRE). In an unfavorable decision dated May 24, 2018, the IRE denied coverage on the basis that the medical records did not meet the requirements of Local Coverage Determination (LCD) L34823. Ex. 1 at 3-4.

Appellant timely requested a hearing before an Administrative Law Judge to review that IRE’s denial of Medicare Part C benefits. Ex. 3. The amount in controversy meets the jurisdictional amount; therefore, there is jurisdiction to hear and decide this case.

I conducted a hearing by telephone on September 5, 2018. At the hearing, Appellant’s interest was represented by Novocure, the Provider, which was in turn represented by Stephanie Hales, Esq. Also appearing for the Provider were Dan McCoy, and Julie Miles, RN (Clinical Specialist), and , the Appellant’s husband. Humana appeared at the hearing through its representative Marcia Taylor and its witness Bryan Carr, M.D. Elizabeth Lemester, M.D., from Humana observed the hearing, but did not testify or participate. I administered oaths to Mr. McCoy, Ms. Miles, Mr. Haas, Ms. Taylor and Dr. Carr. Ms. Miles, Mr. Haas, and Dr. Carr testified at the hearing. I admitted Exhibits 1-5 into the record. During the hearing I heard testimony concerning recent medical test results and asked Appellant to submit that documentation so the record was complete. Humana had no objection. Having received that documentation shortly after the hearing, I now admit it as part of Exhibit 4.

ISSUE

Whether Humana is required to cover an electrical stimulation device used for cancer treatment (HCPCS E0766) provided to the Appellant?

FINDINGS OF FACT

1. The Appellant is a 75 year-old female who has the diagnosis of right frontal glioblastoma. Ex. 2 at 6.
2. On December 4, 2017, the Appellant had a gross total resection of the lesion and a specimen was biopsied. Ex. 2 at 6, 9, 12.
3. From January 18, 2018 to February 26, 2018, Appellant received the following treatments: “Temozolomide and XRT – total dose to the tumor bed to 5940 cGy.” Ex. 2 at 6.
4. In a March 29, 2018 progress note the impression of Sara Grethlem, M.D., was “[i]ncreased perfusion, nodular enhancement, and focal diffusion restriction in the posterior superior margin of the resection cavity is concerning for residual and recurrent neoplasm.” Ex. 2 at 8; *see also* Ex. 2 at 18.

5. Dr. Grethlem provided Adjuvant Temozolomide/Optune TTF on May 3, 2018. Dr. Grethlem's assessment was that Appellant "has evidence of disease progression on the imagining. This is not confined to previously irradiated areas, so I do not believe that it is pseudo progression. She is very early in her therapy in the adjuvant setting, and it is very concerning. . . . The question is really whether or not her current therapy (adjuvant temozolomide and TTF) has had sufficient treatment time to assess it is progressive." Ex. 2 at 2.
6. An August 20, 2018 MRI of Appellant's brain showed that "[t]here has been interval reduction of the confluent T2/FLAIR signal in the right frontal lobe, compatible with decreased surrounding vasogenic edema." Ex. 4.

LEGAL FRAMEWORK

A. Jurisdiction

An individual or organization that is dissatisfied with a reconsideration of a Contractor's initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (Secretary) provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act § 1869(b)(1)(A). The Secretary administers the nationwide hearings and appeals system through the Office of Medicare Hearings and Appeals (OMHA). Administrative Law Judges (ALJs) within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council.

A request for hearing meets the amount in controversy requirement if it comports with 42 C.F.R. § 405.1006(b)(1). A request for hearing is timely if filed within sixty days after receipt of the notice of the Qualified Independent Contractor decision. 42 C.F.R. § 405.1002(a)(1).

B. Scope of Review

"The issues before the administrative law judge include all the issues brought out in the initial, reconsidered or revised determination that were not decided entirely in [the appellant's] favor. However, if evidence presented before or during the hearing causes the administrative law judge to question a fully favorable determination, he or she will notify [the appellant] and will consider it an issue at the hearing." 42 C.F.R. § 405.1032(a).

The ALJ may decide a case on the record and not conduct an oral hearing if the decision is fully favorable, or if the appellant indicates in writing that he does not wish to appear before the ALJ at a hearing. 42 C.F.R. § 405.1038.

C. Standard of Review

"The ALJ conducts a de novo review and issues a decision based on the hearing record." 42 C.F.R. § 405.1000(d).

Principles of Law

A. Statutes and Regulations

According to § 1862(a)(1)(A) of the Social Security Act ("Act"), Medicare may not make a payment under part A or part B for anything which is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

B. Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than an NCD, can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. (*See also* 42 C.F.R. § 405.860). However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that establishes criteria for coverage of selected types of medical items and services in the form of manuals and local coverage determinations (LCDs). Administrative Law Judges are not bound by LCDs, but will give substantial deference to these policies when applicable. (42 C.F.R. § 405.1062). If an Administrative Law Judge does not follow a policy in a particular case, the Administrative Law Judge must explain why in the decision. (42 C.F.R. § 405.1062).

CMS Medicare Managed Care Manual (MMCM), 100-16, Ch. 40 sets forth specific guidance regarding Medicare cost plans.

Although not subject to the force and effect of law, CMS and its contractors issue policies, manuals and guidelines that describe criteria for coverage of selected types of medical items and services in the form of manuals and local coverage determinations (LCDs). 42 C.F.R. § 405.1062 states that an ALJ is not bound by LCDs or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. If an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed. An ALJ decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.

LCD L34823 entitled "Tumor Treatment Field Therapy (TTFT)" provides that TTFT (E0766) will be denied as not reasonable and necessary.

The undersigned notes that the LCD contains a blanket citation to authorities for support but provides no rationale, discussion or criteria upon which exceptions can be made within the context of the LCD, or upon which the LCD is based. Moreover, it does not discuss what authorities it specifically relies upon, nor what the authorities purport to state.

Policy Article A52711 provides additional guidance for TIFT, and seems to provide some inconsistent analysis with the LCD, as follows:

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed- body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary"). Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Code E0766 is in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories. Separate billing of supplies and/or accessories will be denied as unbundling.

The accompanying Policy Article establishes that TTFT is categorized under the Durable Medical Equipment benefit. The article explains that code E0766 describes "devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers." The article further states that TTFT devices are in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories. While it defers to any applicable LCD it seems to confirm categorically that in particular cases such treatments should be found to be medically reasonable and necessary. Additionally, it anticipates that any applicable LCD will provide eligibility criteria.

C. Evidence of Coverage

The Plan at issue is a Medicare Advantage Plan. The Plan's EOC states that as a Medicare health plan, the plan "must cover all services covered by Original Medicare and must follow Original Medicare's coverage rules." Ex. 5 at 43. Covered services include "all the medical care, health care services, supplies, and equipment that are covered by our plan." *Id.*

ANALYSIS

After careful consideration of the evidence and arguments presented, I conclude that the Novocure/Optune treatment is reasonable and necessary for purposes of coverage under Medicare Part C for the Appellant.

An MA plan must provide an enrollee with coverage for all items and services covered by Medicare Part A (except hospice services) and Part B that are available to beneficiaries in the plan's service area. See Section 1852 (a) (1) of the Social Security Act (Act); 42 C.F.R. §§422.100. An MA plan must comply with National Coverage Determinations (NCDs), general coverage guidelines included in original Medicare manuals and instructions, and written coverage decisions of local Medicare contractors with jurisdiction over claims in the geographic area in which services are covered under the MA plan. Therefore, if Medicare does not cover an item or service, unless the plan covers the item or service through supplemental benefits, the Plan is not required to cover the item or service at issue. See 42 C.F.R. § 422.102.

An LCD is program guidance developed by a Medicare contractor and is applicable only in that contractor's service area. An ALJ is not bound by program guidance such as LCDs, program memoranda, or manual instructions. However, an ALJ must give such policies substantial deference if applicable in a particular case. 42 C.F.R. § 405.1062(a). If an ALJ declines to follow a policy in a particular case, the rationale for not following that policy must be explained. 42 C.F.R. § 405.1062(b).

At the hearing Ms. Hales discussed that the Appellant's claim for coverage was denied by Humana and the Part C IRE based on Humana's reliance on the LCD. Hearing Record. Ms. Hales argued that TTFT treatment should be available for Appellant because a departure from the LCD is appropriate here. *Id.* Mr. Hales argued that the plan was required to follow the LCD, but noted that the ALJ has the discretion to decline to follow the policy put forth in an LCD. *Id.* Ms. Hales stated that Appellant has a particularly aggressive cancer and that there are limited treatment options. She stated that there is a broad medical consensus related to TTFT. In regard to Appellant, she started the treatment while this appeals have been pending and she has been well while on the therapy. Appellant would like to continue the therapy. She argued that Appellant's physician is an expert related to this treatment and that the physician stated in the requested for expedited review that TTFT was necessary, which aligns with FDA recommendations. Ms. Hales said that most insurance now covers TTFT. Ms. Hales said that specific to Ms. Haas that she is a good candidate for the TTFT, and that she has tolerated it and has been doing well. Ms. Hales argued that Departure from the LCD should be allowed based on the totality of the circumstances.

Julie Miles, RN, testified regarding the Appellant's symptoms and diagnosis which was glioblastoma, a very aggressive and rare form of brain cancer. *Id.* Ms. Miles testified that in December 2017, Appellant had a gross resection of the tumor and radiation. In March, there was concern of progression and TTFT was approved by the physician since treatment through surgery and radiation had already occurred. By July 2018, the situation had stabilized.

Ms. Miles discussed the recent acceptance by the FDA of TTFT treatment for newly diagnosed and reoccurrences of glioblastoma. *Id.* Ms. Miles also discussed recent studies and positive trials and noted that one study was even aborted mid-stream when it was discovered that the TTFT was so effective, it was determined to be unfair to continue to deny the treatment to the patients in the placebo group. *Id.* Mr. Hales also testified that the NCCN is the recommended compendia for providers of cancer treatments and noted the favorable treatment of TTFT in the NCCN and multiple published articles and journals. Ms. Miles concluded by testifying regarding the benefits of TTFT and how it has impacted the glioblastoma universe through statistically significant improvement in survival rates. *Id.*

, Appellant's husband, testified that Appellant has been on TTFT and that Appellant has had no growth in the cancer and was stable. He stated that he would prefer for Appellant to stay on TTFT.

Bryan Carr, M.D., testified that Medicare Advantage Plans have to follow LCDs and that in this case, TTFT is not medically reasonable and necessary under the applicable LCD.

I agree with Appellant's counsel that the totality of the circumstances in this case support a departure from strictly following the LCD applicable to this case. Appellant initially received surgery and radiation to treat the diagnosed glioblastoma. However, an MRI showed progression of the disease and Appellant's physician determined that TTFT was the most appropriate treatment for the aggressive cancer that Appellant has, which was undeterred following conventional treatments. Ex. 1 at 33-34. The LCD does not explain why it categorically concludes that TTFT is not medically reasonable and necessary; however, the FDA and NCCN provide considered views that TTFT might well be reasonable and necessary as ordered by Appellant's oncologist after surgery and radiation. It is important to note that I do not attempt here to invalidate LCD 34823. Indeed I have no such authority. 42 C.F.R. § 405.1062(c). Rather, looking at the medical facts in this case along with updated medical views of the efficacy of TTFT, it appears that the categorical prohibition LCD 34823 states for TTFT is not warranted in Appellant's particular case. Because LCD 34823 provides no explanation for its approach to TTFT, I cannot conclude, based on the record before me, that TTFT is not medically reasonable and necessary for Appellant.

CONCLUSION OF LAW

1. Based on the totality of evidence of record, I conclude that Tumor Treatment Field Therapy is medically reasonable and necessary for Appellant under Title XVIII of the Social Security Act, Medicare Part C, Medicare Guidelines, and the terms of the health plan.
2. Humana is required to grant Appellant's approval request for the TTFT.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

SEP 19 2018

Dated: _____



Scott Anderson
Administrative Law Judge



**Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Cleveland Field Office
Cleveland, Ohio**

Appeal of:	ALJ Appeal No: 1-7707765284
Beneficiary:	Medicare Part: C
HICN: *****1896A	Before: Gary D. Smith U.S. Administrative Law Judge

DECISION

After carefully considering the evidence presented in the record, a **FAVORABLE** decision is entered for . (hereinafter, the Appellant/Beneficiary).

Procedural History

At all times relevant, the Beneficiary was an enrollee in ARCADIAN Health Plan, Inc./Humana, a Medicare Advantage (MA) Plan (hereinafter, the Plan).

The Beneficiary and/or his physician requested pre-approval of tumor treatment field therapy (E0766), in treatment of the Beneficiary's glioblastoma, stage 4. The Plan denied pre-approval upon initial determination (June 4, 2018) and redetermination.

Maximus Federal Services, a Medicare Qualified Independent Contractor (QIC), issued an unfavorable reconsideration, reasoning: "Medicare specifically excludes coverage for tumor treatment field therapy (E0766) as not medically reasonable and necessary."

The Office of Medicare Hearings and Appeals (OMHA) received the Beneficiary's timely-filed request for an Administrative Law Judge (ALJ) hearing. The amount in controversy satisfies the jurisdictional threshold for a hearing before an ALJ.

On September 19, 2018,, the ALJ conducted a telephonic hearing. The Beneficiary was represented by Stephanie Hales, Esquire (Ms. Hales). Dan McCoy (Mr. McCoy) and Julie Miles (Ms. Miles), of Novacure, were also present on behalf of the Beneficiary. The Plan was not present. The witness(es) were sworn in. All exhibits were admitted into the record without objection. At the close of the hearing, the ALJ kept the record open for seven days to allow the Beneficiary to submit ALJ decisions in support of his position. These documents were received on September 26, 2018, marked as Exhibit 4, and admitted into the record without objection.

Issue

The QIC determined that the Plan is not required to pre-approve and/or allow coverage for the tumor treatment field therapy (E0766), in treatment of the Beneficiary's glioblastoma, stage 4. The Beneficiary argues that the services warrant coverage under the terms of the Plan.

The issue before the ALJ is whether the Plan is required to pre-approve and/or allow coverage for the tumor treatment field therapy (E0766), in treatment of the Beneficiary's glioblastoma, stage 4.

Findings of Fact

The Beneficiary was a 67-year-old male with a history of grade IV astrocytoma in the right frontal lobe with secondary left-sided weakness. (Exh. 2, pgs. 1-6.) This was found on February 28, 2018, status post craniotomy with maximum safe resection and carmustine wafer placement. The disease was not fully resectable. Pathology documents this as a right temporal mass/glioblastoma, grade 4. (Exh 2, pgs. 12-13.)

In the following months, he was treated with temazolamide and radiation therapy. (Exh. 2, pgs. 1-11.) In June, 2018, he started Optune therapy (alternating electrical field therapy) and was tolerating this well. A MRI of the brain showed a possible concern for early progression, but it was noted this could be a recent therapy effect. (*Id.*)

The appeal requests pre-approval for Optune therapy (E0766) , known as tumor treatment field therapy or electrical field therapy.

The NCCN Clinical Practice Guidelines 2016 in Oncology for "Central Nervous System Cancers," include Tumor Treatment Therapy (TTF) treatment for recurrent glioblastoma.

Pursuant to the Food and Drug Administration (FDA), "Radiation therapy and cancer drugs can allow patients to live longer than if they had no treatment. Adding Optune to temozolomide can allow patients to live even longer than with temozolomide alone." https://www.accessdata.fda.gov/cdrh_docs/pdf10/P1000348013d.pdf.

Pursuant to the NIH, "The Food and Drug Administration (FDA) approved TTF for recurrent glioblastoma and newly diagnosed glioblastoma in 2011 and 2015, respectively." <https://www.ncbi.nlm.nih.gov/pubmed/28841803>.

Pursuant to the NIH, "Glioblastoma (GBM) is the most common and aggressive malignant brain tumor in adults. Current treatment options at diagnosis are multimodal and include surgical resection, radiation, and chemotherapy. Significant advances in the understanding of the molecular pathology of GBM and associated cell signaling pathways have opened opportunities for new therapies for recurrent and newly diagnosed disease. innovative treatments, such as tumor-treating fields (TTFields) [Optune] and immunotherapy, give hope for enhanced survival." <https://www.ncbi.nlm.nih.gov/diseases/2491-glioblastoma>.

Pursuant to the American Association for Cancer Research, "Interim data from the first 315 patients enrolled in the trial led the U.S. [FDA] to approve the Optune medical device for newly diagnosed glioblastoma. "Now we are reporting the final results for all 695 patients enrolled on the trial, including long-term outcome. Our data firmly establish the survival benefit of treatment with TTFields," said Stupp. The median overall survival for patients randomly assigned TTFields and temozolomide was 21 months, compared with 16 months for those randomly assigned temozolomide alone. The two-, three-, four-, and five-year survival rates for patients who received TTFields and temozolomide were significantly improved compared with those for patients who received temozolomide alone: 43 percent versus 31 percent; 26 percent versus 16 percent; 20 percent versus 8 percent; and 13 percent versus 5 percent. TTFields showed an effect in all subgroups of patients treated, including the patients who have the most unfavorable prognostic factors." (April 2, 2017.) <https://www.aacr.org/Newsroom/Pages/News-Release-Detail.aspx?ItemID=1029>.

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) § 1869(b)(1)(A).

In implementing this statutory directive, the Secretary has delegated his authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *Id.*

A hearing before an ALJ is only available if the remaining amount in controversy meets a jurisdictional threshold. Additionally, the request for ALJ hearing must be timely filed within sixty days after receipt of the reconsideration. 42 C.F.R. § 405.1002.

B. Scope of Review

Under the Centers for Medicare and Medicaid Services' (CMS) implementation policy for the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. Law 106-554, app. F, 114 Stat. 2763, 2763A-463, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. Law 108-173, 117 Stat. 2066, all initial determinations by CMS contracted Carriers after January 1, 2006, are governed by the ALJ hearing procedures set forth at 42 C.F.R. §§ 405.1000 through 405.1054. 70 Fed. Reg. 11420, 11424-26 (Mar. 8, 2005).

"The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor....The ALJ

may consider a new issue at the hearing if he or she notifies all of the parties about the new issue any time before the start of the hearing. The new issue may include issues resulting from the participation of CMS at the ALJ level of adjudication and from any evidence and position papers submitted by CMS for the first time to the ALJ. The ALJ or any party may raise a new issue; however, the ALJ may only consider a new issue if its resolution - (i) Could have a material impact on the claim or claims that are the subject of the request for hearing; and - (ii) Is permissible under the rules governing reopening of determinations and decisions." 42 C.F.R. § 405.1032.

"If the evidence in the hearing record supports a finding in favor of appellant(s) on every issue, the ALJ may issue a hearing decision without giving the parties prior notice and without holding a hearing. The notice of the decision informs the parties that they have the right to a hearing and a right to examine the evidence on which the decision is based." 42 C.F.R. 405.1038

C. Standard of Review

"The [Office of Medicare Hearings and Appeals]...is staff[ed] with Administrative Law Judges who conduct 'de novo' hearings...." 70 Fed. Reg. 36386 (June 23, 2005). An ALJ qualified and appointed pursuant to the Administrative Procedure Act acts as an independent finder of fact in conducting a hearing pursuant to section 1869 of the Act. (*Id.*)

II. Principles of Law

A. Medicare Part C

The Medicare program is set forth in Title XVIII of the Social Security Act (the Act). Under Title II of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the Medicare Advantage (MA) program was announced as a replacement to the Medicare - Choice (M+C) managed care program. A MA Plan must provide the services currently available under Medicare Parts A and B and may provide additional services if specified in its policy.

While enrolled in a MA plan, an enrollee is entitled to and restricted by the limitations and conditions of that program with respect to Medicare coverage and reimbursement. In turn, the MA plan must make available to an enrollee, or provide reimbursement for, at least all services covered under Part A and Part B of Medicare. 42 C.F.R. § 422.101.

42 C.F.R. § 422.101 states that MA plans must pay for a medical service or item if Original Medicare would pay for it.

42 C.F.R. § 422.111 states that a MA plan must disclose to its enrollees in clear, accurate terms all cost-sharing information (such as copayments, deductibles and coinsurance).

42 C.F.R. § 422.2 states that a copayment is a fixed amount charged to an enrollee on a per-service basis. The coinsurance is a fixed percentage of the total amount paid for a health care service that can be charged to an enrollee on a per-service basis.

In this case, the Plan's Evidence of Coverage (EOC) covers items and services in accordance with the rules of Original Medicare. (Exh. 1.)

B. Medicare Part B

Part B of Title XVIII, the Supplementary Medical Insurance program, provides coverage for a variety of medical services and supplies furnished by physicians, or by others in connection with physicians' services, for outpatient hospital services, and for a number of other specific health-related items and services. Individuals participate voluntarily in the Medicare Part B program and pay a monthly premium.

In relevant part, Section 1861(s) of the Act, identifies "medical and other health services" as including the following items or services: physicians services and diagnostic tests.

C. Local Coverage Determinations

Section 1842(a)(1)(A) of the Act gives the U.S. Secretary of the Department of Health and Human Services (hereinafter the Secretary) the authority to enter into contracts with private entities for the day-to-day operations of the Medicare program. The Administrative Law Judge is bound by the Act at 42 U.S.C. § 1395 et. seq., the Code of Federal Regulations, CMS Rulings, and National Coverage Determinations. While not binding on the Administrative Law Judge, Local Coverage Determinations, LCDs, which are issued by the contractors, are entitled to substantial deference to the extent that they are consistent with the Social Security Act and CMS regulations. See *Lyng v. Payne*, 476 U.S. 926, 939 (1986); 42 C.F.R. § 405.1062.

The Medicare contractor with jurisdiction over the Beneficiary's geographic area has issued LCD L34823, which states that Medicare excludes coverage for tumor treatment field therapy (E0766) as not medically reasonable and necessary.

Analysis

Pursuant to LCD L34823, tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. The regulations direct an ALJ to give "substantial deference" to LCDs. 42 C.F.R. § 405.1062(a). However, the regulations also permit an ALJ to decline to follow a LCD in an individual case. 42 C.F.R. § 405.1062(a). In this case, the ALJ does not give substantial deference to LCD L34823. The ALJ is not challenging the validity or substance of the LCD. The ALJ finds that, based upon the unique facts of this case, the LCD should not be followed.

Research articles, FDA approval, and NIH studies support the conclusion that TTFT (Optune) is safe and effective in treating the Beneficiary's diagnosis of glioblastoma. The NIH identifies glioblastoma as a rare disease with limited treatment options. <https://rarediseases.info.nih.gov/diseases/2491/glioblastoma>. The FDA approved TTF for recurrent glioblastoma and newly diagnosed glioblastoma in 2011 and 2015. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC28841803/>. This reflects successful clinical trials in

which Optune (tumor treatment field therapy (E0766)) in combination with temozolomide allowed patients to live even longer than with temozolomide alone.

The Beneficiary was a 67-year-old male with a history of grade IV astrocytoma in the right frontal lobe with secondary left-sided weakness. On February 28, 2018, he underwent craniotomy with maximum safe resection and carmustine wafer placement. The disease was not fully resectable. Pathology documents his tumor as a right temporal mass/glioblastoma, grade 4. He received radiation treatment with concurrent temozolomide. Due to the nature of his disease, limited treatment options, and favorable outcomes with TTFT, Optune (tumor treatment field therapy (E0766)) is the best FDA approved option for treating his glioblastoma.

Although a specific policy, LCD L34823 does not allow Medicare coverage for Optune, the research provided and unique facts of this case demonstrate that there are other factors to consider in this case that outweigh the application of LCD L34823. The ALJ finds that, in this case, due to the unique facts and medical research specific to this individual case, LCD L34823 should not be followed.

In this case, the Optune device (tumor treatment field therapy (E0766)) meets the requirements for Medicare coverage because the device/services have been shown to be reasonable and necessary for the treatment of glioblastoma. The FDA has approved Optune as being safe and effective for treating glioblastoma. Further, the documentation demonstrates that the use of Optune in this case, used consistent with the FDA indication, can be expected to provide a favorable outcome and higher quality of life for the Beneficiary. The ALJ finds that the tumor treatment field therapy (E0766), in treatment of the Beneficiary's glioblastoma, stage 4 is a covered benefit under the terms of the Plan.

Conclusions of law

Under the circumstances described in this case, tumor treatment field therapy (E0766) is a covered benefit under the terms of the Plan. The Plan is required to pre-approve and allow coverage for the tumor treatment field therapy (E0766), in treatment of the Beneficiary's glioblastoma, stage 4.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim(s) in accordance with this decision.

Dated: OCT 22 2018

SO ORDERED.


Gary D. Smith

U.S. Administrative Law Judge



**Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Irvine, California**

Appeal of:	OMHA Appeal No.: 1-7726450464
Enrollee:	Medicare: Part C
Medicare No.: *****5491A	Before: Marilyn Mann Faulkner U. S. Administrative Law Judge

DECISION

After careful consideration of the evidence and arguments presented in the record and at the hearing, a **FULLY FAVORABLE** decision is entered for "Appellant" and "Beneficiary").

Procedural History

This appeal is before the Office of Medicare Hearings and Appeals ("OMHA") following prior adverse determinations made by the Appellant's Medicare Advantage Organization ("MAO"), Humana Health Plan (MAO), and by the Part C Qualified Independent Contractor ("QIC"), MAXIMUS Federal Services. The MAO and the QIC denied the Appellant's request for coverage of proton beam therapy. (Exh. 1.)

OMHA received the Appellant's request for an administrative law judge ("ALJ") hearing on July 30, 2018. (Exh. 4, p. 1.) The Appellant's Request for an ALJ Hearing satisfies the request for hearing timeliness requirement specified in Title 42 Code of Federal Regulations ("C.F.R.") Section 422.602(b). The amount in controversy in this matter exceeds \$160.00 and thus, the amount in controversy in this appeal satisfies the jurisdictional requirement set forth in Title 42 C.F.R. Sections 422.600 and 422.602(d)(1). Accordingly, OMHA has jurisdiction over this case. (C.F.R. §§ 422.602(b); 422.600; 422.602(d)(1).)

A Notice of Hearing was sent to the Appellant, the QIC and Humana Health Plan (the MAO). (Exh. 4, pp. 10-14.) On September 18, 2018, a telephonic hearing was held in this matter in Irvine, California. At the hearing Stephanie Halles, an attorney for Novocure, Julie Miles, RN, and Dan McCoy, case manager, appeared and testified on behalf of the Beneficiary. Dr. Elizabeth Lemaster, MD, and Marsha Taylor, Grievance and Appeals Specialist, appeared and testified on behalf of Humana. The record was held open to allow the Appellant an opportunity to submit additional documentation. The Appellant submitted those documents on October 5, 2018 and they are admitted into the record as Exhibit 5. (Hearing CD).

Issue

Whether Humana Health Plan is required to provide coverage of tumor treatment field therapy (TTFT) for the Beneficiary pursuant to the Medicare Part C provisions of Title XVIII of the Social Security Act and implementing regulations and under the terms of the MAO's Evidence of Coverage.

Findings of Fact

At all times relevant herein, the Appellant/Beneficiary was a member of the MAO and was enrolled in its health plan as of January 1, 2018. (Hearing CD; Exh. 1, p. 10).

The Beneficiary, a 68-year-old male, has a diagnosis of brain cancer (malignant neoplasm of brain unspecified), specifically a glioblastoma multiforme (GMB) brain tumor. According to an evaluation report by Dr. Mark Andersen on February 14, 2018, this cancer was newly diagnosed as a grade IV GBM in January 2018 after pathology from resection of a large right-sided temporal lobe mass on January 12, 2018. Post-operatively, he had a complicated hospital course which included left hemiparesis and was discharge to t rehab facility. The patient underwent radiation and chemotherapy treatment. A post-operative MRI, dated January 18, 2018, was performed to establish a baseline for stability. The MRI revealed suspicious findings for minimal residual tumor to be evaluated on follow-up examinations. (Exh. 2, pp. 3-6).

A subsequent MRI, dated April 25, 2018, stated that the tumor infiltrate had decreased with decreased mass effect. It stated: "Increased size of both solid nodule, peripheral enhancement which is linear and nodular, and cystic components to the right temporal mass highly concerning for tumor progression, Persistent surrounding edema and/or tumor infiltrate has decreased with decreased mass effect.....Midline shift and mass effect has greatly improved from prior MRI." (Exh. 2, pp. 14-16).

Optune tumor treatment field therapy was ordered on April 25, 2018 by Dr. Anderson for the diagnosis of glioblastoma (C71.90). The preferred treatment start date was May 9, 2018. (Exh. 2, pp. 17-18.)

The medical record included treatment and imaging records for the Beneficiary's brain cancer diagnosis which have been summarized above. (Exh. 2).

Following the hearing, the Appellant submitted the Beneficiary's most recent MRI report, dated August 29, 2018, which has been admitted to the record as Exhibit 5, pp. 64-65. The MRI report indicated it was in comparison with the MRI performed on May 21, 2018. The impression was: "Mild interval increase in size of right frontotemporal mass and surrounding tumor infiltrate and/or edema. Slight increase in mass effect and degree of midline shift." (Exh. 5, pp. 64-65).

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services ("HHS"), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. (Social Security Act § 1869(b)(1)(A).)

In implementing this statutory directive, the Secretary has delegated her authority to administer the nationwide hearings and appeals systems for the Medicare program to OMHA. (70 Federal Register 36386, 36387 (June 23, 2005).) The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. (42 C.F.R. § 422.608.) Any party to the hearing who is dissatisfied with the ALJ decision may request that the Medicare Appeals Council review the ALJ's decision. (*Ibid.*)

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the Appellant's favor. However, if evidence presented before or during the hearing causes the ALJ to question a favorable portion of the determination, he or she may notify the parties before the hearing and may consider it an issue at the hearing. (42 C.F.R. § 405.1032(a).)¹

C. Standard of Review

According to 42 C.F.R. Section 405.1000(d), the ALJ conducts a de novo review and issues a decision based on the hearing record.

II. Principles of Law

A. Statutes and Regulations

Section 1833 of the Act requires a claim for Medicare payment to include sufficient documentation to determine whether payment is due and the amount of payment.

Section 1862(a)(1)(A) of the Act provides that Medicare payment may be allowed only for services that are considered reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

The Medicare program is administered through CMS, a component of HHS. CMS contracts with organizations to offer plans under the Medicare Advantage program. (Act § 1857.) The Act provides that an MAO must provide the coverage that would be available to a beneficiary under

¹ The regulations in part 405 of the C.F.R. apply to part 422, unless part 422 provides otherwise. (42 C.F.R. § 422.562(d).)

Parts A and B of the Act (except hospice care) ["basic benefits"] as well as certain additional benefits under specified circumstances. (Act § 1852(a)(1).)

In providing "basic benefits," an MAO must comply with national coverage determinations ("NCD") issued by CMS, "[g]eneral coverage guidelines included in original Medicare manuals and instructions unless superceded by operational policy letters or regulations . . .," and local policy coverage determinations issued by Medicare intermediaries and carriers with jurisdiction for claims in the geographic area.² (42 C.F.R. § 422.101(b).)

Pursuant to Title 42 C.F.R. Section 405.1062(a), an ALJ is not bound by a LCD, but will give substantial deference to a LCD if it is applicable to a particular case. According to Title 42 C.F.R. Section 405.1062(b), if an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed. An ALJ decision to disregard such a policy applies only to the specific claim being considered and does not have any precedential effect. (42 C.F.R. § 405.1062(b).)

B. Policy and Guidance

Section 1871(a)(2) of the Social Security Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than a National Coverage Determination (NCD), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. *See also* 42 C.F.R. § 405.860. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local medical review policies (LMRPs) or local coverage determinations (LCDs). An ALJ is not bound by an LCD, but must give substantial deference to the policy. 42 C.F.R. § 405.1062.

CGS Administrators' LCD L34823 states the following regarding Tumor Treatment Field Therapy:

Coverage Indications, Limitations, and/or Medical Necessity

...

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

The Policy Article A52711 states the following regarding tumor treatment field therapy:

CODING GUIDELINES

Code E0766 describes devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers.

This code is inclusive of all associated supplies necessary for the effective use of

² MAOs covering more than one local coverage geographic area may adopt the local policy that is most beneficial to plan enrollees as a uniform policy for all plan enrollees. (42 C.F.R. § 422.101.)

code E0766 including, but not limited to, transducers/surface electrodes, lead wires, adhesive patches, connectors, conductive gel and skin preps.

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

Pursuant to Title 42 C.F.R. Section 405.1062(a), an ALJ is not bound by a LCD, but will give substantial deference to a LCD if it is applicable to a particular case. According to Title 42 C.F.R. Section 405.1062(b), if an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed. An ALJ decision to disregard such a policy applies only to the specific claim being considered and does not have any precedential effect. (42 C.F.R. §405.1062(b).)

C. Evidence of Coverage

An MAO is required to disclose to its enrollees, in clear, accurate, and standardized form, certain information about its available health plans including the service area, benefits, and exclusions from coverage. (See Act § 1852(c); see also 42 C.F.R. § 422.111).

The MAO's Evidence of Coverage ("EOC") provides that the MAO covers items and services consistent with Medicare coverage. (Exh. 1.)

Analysis

At issue in this appeal is whether the Humana Health Plan must approve and provide coverage of the tumor treatment field therapy (E0766) for the treatment of the Beneficiary's brain cancer, specifically glioblastoma multiforme (or "GBM") tumor.

Prior Determinations

The Beneficiary's physician ordered Optune therapy on April 25, 2018. The Health Plan made an initial denial of the request on May 4, 2018. The Health Plan denied the request on the basis that LCD L34823 states the therapy is not medically reasonable and necessary. The denial stated that: "Medicare rule says tumor treatment field therapy will be denied as not reasonable and necessary." (Exh. 1, pp. 14-15.)

The Appellant requested reconsideration of the initial determination on May 16, 2018. The Health Plan upheld its previous denial on May 17, 2018 stating that LCD L34823 states that tumor treatment field therapy is not medically reasonable and necessary and that Medicare considers the treatment to be ineffective. The Health Plan forwarded the appeal to Maximus Federal Services, the QIC, for independent review. (Exh. 2, pp. 10-11).

The QIC issued an unfavorable reconsideration decision on May 18, 2018. It held that the Health Plan was not required to cover the Beneficiary's request for tumor treatment field therapy. The QIC explained in relevant part:

Medicare says tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. Based on this information, we decided that Medicare rules for coverage of tumor treatment field therapy (E0766) have not been met. Therefore, we decided that Humana does not have to pre-approve tumor treatment field therapy (E0766) for V. Magee. (Exh. 1, p. 3.)

Hearing Testimony

At the September 18, 2018 telephonic hearing, Stephanie Halles, attorney for Novocure, argued the case on behalf of the Appellant. She emphasized that unlike the Health Plan, the ALJ is not bound by the LCD and that the ALJ must give deference to LCDs but may deviate based on the particular facts of the case. Ms. Halles argued that in this case, departure from the LCD was warranted due to the particular circumstances in this case. (Hearing CD).

Ms. Miles, Specialist for Novocure and an RN, also testified for the Appellant. Ms. Miles provided the facts of this case with respect to the diagnosis of this rare and highly aggressive tumor. She indicated that there were limited treatment options available for GBM treatment and that treatment consisted of resection, radiation and chemotherapy, and that subsequent complications and recurrence were likely. She provided a summary of the Beneficiary's clinical condition in this case as reflected in the medical documentation in the record (as summarized in the Findings of Fact above). She noted that he was diagnosed with GBM per pathology results of the resection that was performed on January 12, 2018 and noted that he had a negative MGMT result, also referred to as "unmethylated" MGMT promoter status. The MGMT stats refers to a gene mutation that, when absent (i.e., negative MGMT result), has been shown to be associated with reduced responsiveness of the tumor to chemotherapy. (Hearing CD).

Ms. Miles indicated that the Beneficiary had begun the standard of care protocols for newly diagnosed GBM which consisted of concurrent chemotherapy and radiation with Temodar on February 14, 2018 and was completed on April 6, 2018. On April 25, 2018, his physician ordered Optune therapy to treat his GBM. The prescription specified a preferred Optune treatment start date of May 9, 2018, which Ms. Miles indicated was consistent with the NCCN-recommended course of treatment for newly diagnosed GBM, which was to begin Optune with concurrent Temodar approximately one month after completing chemo-radiation with Temodar. (Hearing CD; Exh. 5, pp. 3-5).

She noted that in contrast to the QIC decision, the Optune treatment has been approved by the FDA and is the recommended treatment for the Beneficiary's diagnosis per NCCN guidelines. She noted that Optune therapy had been approved by the FDA in 2011 for the treatment of recurrent GBM and approved in 2015 for the treatment of newly diagnosed GBM. She stated that NCCN guidelines recommend the use of tumor treatment field therapy as a standard of care in patients with newly diagnosed and recurrent GBM. She stated that in this case, the Beneficiary was MGMT negative which was even greater indicator of use of the drug since a negative result had been shown to be associated with reduced responsiveness of the tumor to chemotherapy alone. She argued that given the aggressive nature of the Beneficiary's brain cancer and the lack of other available treatment, tumor treatment field therapy was the best FDA approved option the Beneficiary had at this time. (Hearing CD.)

Ms. Miles indicated that there was broad medical consensus on the effectiveness and benefits of TTFT; and that not only was the treatment included in NCCN's guidelines as a Category 1 recommended treatment for newly diagnosed GBM, over 800 leading oncology centers across the US were certified to prescribe and provide Optune TTFT, which reflects the widespread use and acceptance of the treatment. She further noted that Optune TTFT was covered for uses consistent with its FDA-approved indications under published coverage policies by many commercial insurance companies-including Humana for its commercial (non-Medicare) plan subscribers-as well as a number of state Medicaid programs, further demonstrating broad medical consensus. (Hearing CD.)

Medicare Rules and Policies Regarding Coverage of Tumor Treatment Field Therapy

As indicated above, a Health Plan must pay for a service if Original Medicare would pay for such service. Medicare provides coverage for items and services that are reasonable and necessary to diagnose or treat an illness or condition. CMS has not issued specific coverage criteria in the form of an NCD but the CMS contractor in the local coverage area at issue, CGS Administrators, has issued an LCD regarding TTFT therapy. The LCD states the following: "Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary."

As stated above, and as argued by the Appellant, an ALJ is not bound by a LCD, but will give substantial deference to a LCD if it is applicable to a particular case (Title 42 C.F.R. Section 405.1062(a). According to Title 42 C.F.R. Section 405.1062(b), if an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed. An ALJ decision to disregard such a policy applies only to the specific claim being considered and does not have any precedential effect. (42 C.F.R. §405.1062(b).)

FDA Approval of Optune TTFT Therapy

Per FDA documentation submitted by the Appellant and the FDA website, Optune therapy is FDA-approved for recurrent and newly diagnosed glioblastoma multiforme (GBM) brain tumors. Optune was FDA-approved through FDA premarket approval process (PMA) in April 2011 for patients diagnosed with recurrent glioblastoma. As indicated by the Appellant, Optune was approved through the PMA pathway, which is the most stringent pathway for approval of devices and that only 2% of medical devices are approved through the PMA pathway. The FDA described the PMA pathway stating: "OMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s)."³

In October 2015, the FDA approved Optune for treatment of newly diagnosed GBM. The approval was based on the results of a randomized controlled trial (called EF-14 Trial) of 695 patients comparing Optune plus temozolomide to temozolomide alone in patients with newly diagnosed GBM. (See Exh. 5, pp. 10-18).

³ FDA,
<https://www.fda.gov/MedicalDevicesDeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm>

NCCN Guidelines

Optune is included in the National Comprehensive Cancer Network (NCCN) guidelines with a Category 2B consensus recommendation for recurrent glioblastoma and a Category 1 recommendation, which reflects uniform consensus based on high level of evidence, for newly diagnosed GBM in combination with temozolomide. (Exh. 5, pp. 19-23).

Peer-Reviewed Literature Submitted by the Appellant

Journal of the American Medical Association (JAMA) (Published December 15, 2015): Maintenance Therapy with Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma.

The article published the interim results of the EF-14 Trial, as mentioned above under the FDA approval. The results showed superior efficacy both in progression-free survival as well as overall survival. According to the literature, significantly, the EF-14 trial was the first trial in more than a decade to demonstrate statistically and clinically significant extension of overall survival in patients with newly diagnosed GBM regardless of patient characteristics. The interim data of EF-14 trial showed the following:

- Patients treated with TTFT together with temozolomide demonstrated a significant increase in progression free survival compared to temozolomide alone
- Patient treated with TTFT together with temozolomide also demonstrated a significant increase in overall survival compared to temozolomide alone
- The percentage of patient alive at 2 years in the TTFT together with temozolomide arm was 43% compared to 29% in the temozolomide alone arm.

(Exh. 5, pp. 24-32).

The Journal of the American Medical Association (Published December 19, 2017): Effect of Tumor-Treating Fields Plus Maintenance Temozolomide vs Maintenance Temozolomide Alone on Survival in Patients with Glioblastoma.

The final analysis of the EF-14 trial was published in JAMA in December 2017 and showed that the overall survival and progression free survival were each significantly extended by 37% for patients who received Optune plus temozolomide compared to patient who received temozolomide alone. The analysis demonstrated a greater than one in eight chance of 5 year survival for patients with newly diagnosed GBM treated with Optune and temozolomide. The statistically significant benefit of Optune with temozolomide on overall survival was seen in all pre-specified patient subgroups, regardless of prognostic factors such as age, performance status, MGMT promotor methylation and extent of resection.

The article indicated that patients treated with Optune plus temozolomide experienced overall survival of 20.9 months versus 16 months for patients treated with temozolomide alone. The 5-year survival rate increased from 5% to 13% for patients with Optune with temozolomide versus patient treated with temozolomide alone. There was no increase in systemic adverse events from Optune plus temozolomide versus temozoloide alone.

(Exh. 5, pp. 33-43).

Based on the Evidence in the Record, I find that Tumor Treatment Field Therapy for Treatment of the Beneficiary's Glioblastoma Multiforme Brain Cancer is Medically Reasonable and Necessary per Medicare Rules and Policy

In this case, the record shows that the Beneficiary was recently diagnosed with brain cancer, specifically glioblastoma multiforme or "GBM," a rare and highly aggressive cancer. Following standard of care protocol of treatment that consisted of a combination of chemotherapy and radiation with Temodar, the Beneficiary's physician, Dr. Anderson, ordered tumor treatment field therapy in combination with Temozolomide (or Temodar).

In the letter from Dr. Anderson dated May 7, 2018, he indicated that tumor treatment field therapy should be approved for this Beneficiary as it was the standard of treatment for patients with newly diagnosed and recurrent GBM and that NCCN guidelines had been updated in 2015 to include TTFT treatment for such individuals. Dr. Anderson explained that following the Beneficiary's course of chemotherapy and radiation treatment, TTFT was the best FDA approved treatment option at this time for treating his GBM. Dr. Anderson concluded that, "Optune is the only promising option for him at the present time" and that based on his orphan disease status, limited treatment options and the favorable outcomes and higher quality of life afforded with this treatment, TTFT should be covered for the Beneficiary. (See Exh. 1, pp. 24-26).

Based on the peer-reviewed articles, NCCN guidelines, medical literature and arguments presented in the record and at the hearing, it is clear that TTFT for patients with recurrent and newly diagnosed GBM is the standard of care protocol following resection and combination of chemotherapy and radiation treatment. As stated above, the FDA approved TTFT treatment for patients with recurrent GBM in 2011, and then later approved TTFT treatment for patient with newly diagnosed GBM in 2015. The FDA approvals were based on large randomized trials which had shown proven results of the effectiveness of TTFT. These trials are further discussed and widely accepted as treatment for GBM, as published in the Journal of American Medical Association in both 2015 and in 2017 (See above for the summary). TTFT has also been included as the stand of care in appropriate individuals in the NCCN Clinical Practice Guidelines that were updated in 2015. The NCCN guidelines provide a Category 2B consensus recommendation for TTFT treatment for recurrent GBM and a Category 1 recommendation for TTFT treatment for newly diagnosed GBM concurrent with temozolomide. A Category 1 NCCN recommendation reflects *uniform consensus based on high level of evidence*. Furthermore, more than 800 leading oncology centers across the U.S. are certified to prescribe and provide Optune TTFT, reflecting widespread use and acceptance by relevant experts and specialists nationwide. It is also interesting to note that Optune TTFT has been covered for uses consistent with FDA-approved indications under published coverage policies by many commercial insurance companies-including Humana for its commercial (non-Medicare) plan subscribers-as well as a number of state Medicaid programs, all of which further demonstrates broad medical consensus.

Based on the above, I find that the use of tumor treatment field therapy for the treatment of the Beneficiary's GBM brain tumor is medically reasonable and necessary. As indicated by Dr. Anderson, the Beneficiary's treatment options are limited and TTFT has been proven to be effective for the Beneficiary's clinical condition. With use of TTFT, in combination with

temozolomide, the data and medical consensus shows that the Beneficiary would be provided a greater quality of life as well as increased survival rate. In this case, given the aggressive nature of the GBM tumor, it appears from all the literature that TTFT is the Beneficiary's most promising FDA-approved treatment option available to him and that this treatment option has been widely accepted as the standard of treatment in patients with recurrent and newly diagnosed GBM.

Thus, I find that the Appellant's coverage request for tumor treatment field therapy for the treatment of GBM brain cancer is medically reasonable and necessary in this case. I have taken into account the applicable LCD and have declined to follow it in this case for the extensive reasons I have outlined above.

Conclusions of Law

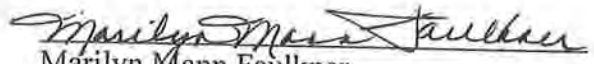
The Health Plan is required to provide coverage for tumor treatment field therapy for the treatment of the Beneficiary's glioblastoma multiforme (GBM) brain tumor cancer pursuant to the Medicare Part C provisions of Title XVIII of the Social Security Act and implementing regulations and policies and under the terms of the Health Plan's Evidence of Coverage.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED

Dated: OCT 30 2018


Marilyn Mann Faulkner
U. S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, Missouri

Appeal of: }	ALJ Appeal No.: 1-7755211044
Enrollee:	Medicare Part: C
HICN: ****9387A	Before: Thomas C. Strafuss U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, a **FAVORABLE** decision is entered for Appellant/Enrollee,

PROCEDURAL HISTORY

Enrollee disputes the decision of Humana Insurance Company, a Medicare Advantage (“MA”) plan, to deny approval of payment for tumor treatment field therapy. On June 22, 2018, Humana reexamined Enrollee’s request for reimbursement for tumor treatment field therapy and affirmed the initial denial. (Exh. 1, pp. 15-17) On July 27, 2018, MAXIMUS Federal Services, a Qualified Independent Contractor (“QIC”), evaluated the claim and issued a decision upholding Humana’s decision on the same grounds. (Exh. 1, pp. 1-2)

The Office of Medicare Hearings and Appeals (“OMHA”) received Enrollee’s timely request for a hearing on August 3, 2018. The requested hearing was held via telephone on September 19, 2018. Julie Miles and Stephanie Hales appeared telephonically on behalf of Novocure. Marcia Taylor and Bryan Carr, M.D., appeared telephonically on behalf of Humana. The case file was admitted into the record without objection.

ISSUE

Whether or not the plan coverage provisions have been met and whether or not payment is warranted.

FINDINGS OF FACT

The following facts were established by a preponderance of the evidence:

1. Enrollee, a 70 year old male, has been diagnosed with glioblastoma multiforme of the brain (ICD-10 code: C71.3). (Exh. 2, pp. 1-18) Enrollee is now requesting approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment provided through Optune, an out of network supply store. (*Id.*)
2. Enrollee has been enrolled in a Humana Choice H5216-078 (PPO). (Exh. 1, p. 68)
3. On June 22, 2018, Humana denied Enrollee's request for approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment and affirmed that decision in redetermination. (Exh. 1, pp. 15-17) Humana's reason for denial was that Local Coverage Determination ("LCD") L34823 regarding tumor treatment field therapy states that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. (*Id.*)
4. On July 27, 2018, the QIC examined Enrollee's claim and affirmed Humana's denial of coverage. (Exh. 1, pp. 1-2)

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services, provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. *See* Social Security Act (the Act), Title XVIII, § 1869(b)(1)(A); *see also* 42 C.F.R. § 405.1014. The Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, unless later reviewed by the Medicare Appeals Council. *Id.*

To be considered timely, the request for hearing must be received by OMHA within sixty days after an appellant receives the QIC's reconsideration decision. An appellant is presumed to have received the QIC's reconsideration five days after the date noted on the first page of the reconsideration unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3).

B. Scope of Review

The ALJ considers all issues not decided entirely in the appellant's favor at any prior level of review. 42 C.F.R. § 405.1032. The ALJ may give notice to the parties if any other issue will be addressed at the hearing. *Id.* The ALJ may also issue a decision on the record on his or her own

initiative if the evidence in the hearing record supports a fully favorable finding. 42 C.F.R. § 405.1000(g) and § 405.1038(a).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue. 42 C.F.R. § 405.1000(d) and Section 557 of the Administrative Procedures Act. A *de novo* review requires the ALJ to review and evaluate the evidence without regard to the findings in the prior determinations on the claim and make an independent assessment in reliance upon the evidence and controlling laws. All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Act and applicable implementing regulations, are binding on the ALJ. 42 C.F.R. § 405.1063.

An appellant has the burden of proving each element of a Medicare claim by a preponderance of the evidence (satisfied through the submission of sufficient evidence in accordance with Medicare rules). See § 1814(a)(1), § 1815(b), and § 1833(e) of the Act; see also 42 C.F.R. § 424.5(a)(6), § 405.1018, § 405.1028, and § 405.1030.

II. Principles of Law

The Medicare program, Title XVIII of the Social Security Act, is administered through the Centers for Medicare and Medicaid Services, a component of the United States Department of Health and Human Services (“HHS”). Title XVIII, § 1832 of the Act describes the scope of benefits provided for by Medicare and provides that those benefits shall include “medical and other health services.” In addition, § 1862(a)(1)(A) of the Social Security Act provides for coverage and payment for those services and supplies only when those services or supplies are considered to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

The obligations of a Medicare Advantage (“MA”) Organization to its enrollees are set forth in §1852 of the Act. 42 C.F.R. §422 establishes standards, requirements, limitations, and procedures for Medicare services furnished or paid for via MA plans. Pursuant to 42 C.F.R. §422.100, MA Organizations must provide their members with the same benefits provided under Parts A and B of Medicare. According to 42 C.F.R. § 422.111, MA Organizations are required to make certain disclosures to its enrollees regarding its services and benefits. These disclosures include the plan’s service area, benefits, and exclusions from coverage. *Id.*

Local Coverage Determination (“LCD”) L34823 regarding tumor treatment field therapy states:

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

ANALYSIS

Enrollee, a 70 year old male, has been diagnosed with glioblastoma multiforme of the brain (ICD-10 code: C71.3). (Exh. 2, pp. 1-18) Enrollee is now requesting approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment provided through Optune, an out of network supply store. (*Id.*) Enrollee has been enrolled in a Humana Choice H5216-078 (PPO). (Exh. 1, p. 68)

On June 22, 2018, in redetermination, Humana denied Enrollee's request for approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment. (Exh. 1, pp. 15-17) Humana's reason for denial was that Local Coverage Determination ("LCD") L34823 regarding tumor treatment field therapy states that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. (*Id.*) On July 27, 2018, the QIC examined Enrollee's claim and affirmed Humana's denial of coverage. (Exh. 1, pp. 1-2)

The obligations of a Medicare Advantage ("MA") Organization to its enrollees are set forth in §1852 of the Act. 42 C.F.R. §422 establishes standards, requirements, limitations, and procedures for Medicare services furnished or paid for via MA plans. Pursuant to 42 C.F.R. §422.100, MA Organizations must provide their members with the same benefits provided under Parts A and B of Medicare.

The Medicare Contractor CGS Administrators, LLC, created a Local Coverage Determination addressing the issue in this case. That LCD simply states that tumor treating field therapy will be denied as not reasonable and necessary. There is no additional detail or guidance contained within the LCD as to why tumor treatment field therapy should not be compensated by Medicare. The only substance is a reference section entitled "Sources of Information and Basis for Decision." That section lists seventeen separate citations which presumably support the summary conclusion that tumor treating fields therapy is not reasonable and necessary. The list is noteworthy in that the most recent citation is from 2013.

Pursuant to section 1869(f)(2) of the Act, Administrative Law Judges are generally required to give substantial deference to Local Coverage Determinations. If an ALJ does not follow an applicable LCD, an explanation must be given. The ALJ chooses to deviate from the LCD for the following reasons. The FDA issued a premarket approval of Optune (a tumor treatment field therapy device) consistent with the prescribed use by the treating physician on November 2, 2015. (Exh. 4, pp. 10-11)¹ FDA approval generally means the treatment has been deemed safe and effective. The most recent phase three clinical trial submitted by Novocure,² published in December 2015, shows that this treatment is effective because it significantly prolongs the disease progression of glioblastoma, and increases the overall odds of survival. The 2015 study is given greater weight than the LCD both because it is recent proof of efficacy and because the LCD lacks any substantive guidance. Further, the 2018 National Comprehensive Cancer Network ("NCCN") Guidelines allow for alternating use of electric field therapy with temozolomide when treating glioblastoma. (Exh. 2, pp. 20-21.) Finally, the Enrollee suffers from glioblastoma, which is the very condition/cancer this device is designed to treat. Therefore the

¹ The FDA had issued an earlier approval for Optune (NOVOTFF -100A System) on May 6, 2011. The approval was limited to the recurrence of glioblastoma multiform after receiving chemotherapy. The current FDA approval includes newly diagnosed GBM following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy. (*Id.*)

² Stupp R., Taillibert S., Kanner A., et al. Maintenance Therapy With Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma: A Randomized Clinical Trial. *JAMA*. 2015; 314(23): 2535-2543. Doi:10.1001/jama.2015.16669. See <http://jama.jamanetwork.com/article.aspx?articleid=2475463>

ALJ concludes that tumor treating field therapy was medically reasonable and necessary in this case, and Medicare covers this service.

The same result would be reached under traditional Medicare.

The undersigned concludes that Medicare coverage is available for the tumor treatment field therapy requested by the Enrollee. The services requested are covered under Medicare Parts A or B and thus Medicare Part C coverage must be approved.

CONCLUSIONS OF LAW

The undersigned concludes Humana does have to cover the tumor treatment field therapy requested by the Enrollee.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim herein in accordance with this decision.

SO ORDERED,

Dated: SEP 27 2018



Thomas C. Strafuss

U.S. Administrative Law Judge



Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Irvine Field Office
Irvine, California

Appeal of:	ALJ Appeal No.: 1-8215420871
Beneficiary:	Medicare Part: C
Medicare Advantage Organization (MAO): Humana	Before: Marilyn Mann Faulkner U.S. Administrative Law Judge
HICN: *****0782A	

DECISION

After careful consideration of the evidence and arguments presented in the record and at the hearing, a **FAVORABLE** decision is entered for : (Appellant and Beneficiary).

Procedural History

The Appellant submitted a request pre-approval for Optune Tumor Treatment Field Therapy (Optune TTFT), billed as electrical stimulation device used for cancer treatment (E0766). Humana, the MAO, denied the request on initial determination and redetermination. On January 4, 2019 Maximus Federal Services, the Qualified Independent Contractor (QIC) issued an unfavorable reconsideration decision (Exh. 1).

The Appellant's timely filed request for Administrative Law Judge Hearing (ALJ) was received on January 10, 2019. The amount in controversy meets the jurisdictional requirement. Accordingly, OMHA has jurisdiction to hear this appeal.

On February 28, 2019, a telephonic hearing was held at the Office of Medicare Hearings and Appeals (OMHA) Irvine Field Office in Irvine, California. Bridget Noonan, Attorney, represented the Appellant. Tim Parks, R.N. and Dan McCoy, Case Manager, appeared and testified on behalf of the Appellant. Dr. Bryan Carr, Medical Director and Marcia Taylor, Appeals and Grievance Specialist, appeared and testified on behalf of Humana. Exhibits 1 through 5 were admitted into evidence without objection.

Additional documentation from the MAC was submitted by the Appellant with the Request for Hearing and is included in the administrative record as part of Exhibit 5. Good cause exists for admission of the new evidence under 42 C.F.R. § 405.1018 at the ALJ level because the evidence is material to an issue addressed in the QIC's reconsideration and was not available until after the reconsideration request was submitted.

Issue

The issue to be decided is whether under the provisions of Title XVIII of the Social Security Act (Act) and implementing regulations, Humana must approve the Appellant's request for pre-authorization for Optune TTFT, billed as electrical stimulation device used for cancer treatment (E0766).

Findings of Fact

The Appellant was newly diagnosed with a glioblastoma (GBM) in April 2018. She was treated with surgery, radiation, and chemotherapy. The Appellant's physician recommended treating her with Optune TTFT (Exh. 1, pp. 11-13 and Exh. 5, p. 5).

The August 7, 2018 letter from CGS, in response to a request for formal reconsideration of LCD L34823 for TTFT, acknowledged that LCD L34823 did not address newly diagnosed GBM. The MAC stated that it would complete the reconsideration of the LCD by September 18, 2018 (Exh. 5, pp. 10-12).

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Section 1869(b)(1)(A) of the Act.

In implementing this statutory directive, the Secretary has delegated authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *See* 74 Fed. Reg. 65296 (December 9, 2009). A hearing before an ALJ is available only if the remaining amount in controversy meets the jurisdictional amount. 42 Code of Federal Regulations (C.F.R.) § 422.600(b). A request for hearing is timely if filed within sixty days after receipt of the reconsideration decision. 42 C.F.R. § 422.602(b).

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. However, if evidence presented before the hearing causes the ALJ to question a fully favorable portion of the determination, the ALJ will notify the parties before the hearing and will consider it an issue at the hearing.

C. Standard of Review

An ALJ conducts a de novo review and issues a decision based on the hearing record. 42 C.F.R. § 405.1000(d).

II. Principles of Law

A. Statutes and Regulations

Section 1831 of the Act established the Supplementary Medical Insurance program (Medicare Part B) to provide medical insurance benefits for aged and disabled individuals who elect to enroll in the program. Section 1832 of the Act provides for coverage of medical and other health services. Section 410.10 of Title 42 of the C.F.R. allows Medicare coverage for medical and other health services, including medical supplies, appliances, and devices and durable medical equipment.

Section 1862(a) of the Act provides that no payment may be made under Part A or Part B for any expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

The obligations of a MAO to its enrollees are set forth in Section 1852 of the Social Security Act and the implementing regulations in 42 C.F.R. Part 422.

Pursuant to 42 C.F.R. § 422.101, each MAO must provide coverage for all services that are covered by Part A and Part B of Medicare and that are available to enrollees residing in the plan's service area.

42 C.F. R §405.1062 - Applicability of local coverage determinations and other policies not binding on the ALJ or attorney adjudicator and Council provides:

(a) ALJs and attorney adjudicators and the Council are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.

(b) If an ALJ or attorney adjudicator or Council declines to follow a policy in a particular case, the ALJ or attorney adjudicator or Council decision must explain the reasons why the policy was not followed. An ALJ or attorney adjudicator or

Council decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.

(c) An ALJ or attorney adjudicator or the Council may not set aside or review the validity of an LMRP or LCD for purposes of a claim appeal. An ALJ or the DAB may review or set aside an LCD (or any part of an LMRP that constitutes an LCD) in accordance with part 426 of this title.

42 C.F.R. §426.300 Review of LCDs, NCDs, and deemed NCDs provides:

(a) Upon the receipt of an acceptable LCD complaint as described in §426.400, an ALJ conducts a review of a challenged provision (or provisions) of an LCD using the reasonableness standard.

(b) Upon the receipt of an acceptable NCD complaint as described in §426.500, the Board conducts an NCD review of a challenged provision (or provisions) of an NCD using the reasonableness standard.

(c) The procedures established in this part governing the review of NCDs also apply in cases in which a deemed NCD is challenged.

42 C.F.R. §426.310 LCD and NCD reviews and individual claim appeals provide:

(a) LCD and NCD reviews are distinct from the claims appeal processes set forth in part 405, subparts G and H; part 417, subpart Q; and part 422, subpart M of this chapter.

(b) An aggrieved party must notify the ALJ or the Board, as appropriate, regarding the submission and disposition of any pending claim or appeal relating to the subject of the aggrieved party's LCD or NCD complaint. This reporting obligation continues through the entire LCD or NCD review process.

42 C.F.R. §426.320 Who may challenge an LCD or NCD.

(a) Only an aggrieved party may initiate a review of an LCD or NCD (including a deemed NCD), or provisions of an LCD or NCD by filing an acceptable complaint.

(b) Neither an ALJ nor the Board recognizes as valid any attempt to assign rights to request review under section 1869(f) of the Act.

B. Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than an National Coverage Determination (NCD), can establish or change a substantive legal standard governing the scope of benefits or payment for

services under the Medicare program. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local medical review policies (LMRPs) or Local Coverage Determinations (LCDs).

ALJs are not bound by LCDs, LMRPs, or CMS program guidance such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.

CGS LCD L34823 – Tumor Treatment Field Therapy (TTFT) (Revision Effective Date Jan. 1, 2017) provides in part:

Coverage Indications, Limitations, and/or Medical Necessity

...

The purpose of a Local Coverage Determination (LCD) is to provide information regarding “reasonable and necessary” criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the “reasonable and necessary” criteria contained in this LCD there are other payment rules, which are discussed in the following documents that must also be met prior to Medicare reimbursement:

For the items addressed in this LCD, the “reasonable and necessary” criteria, based on Social Security Act §1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. (Emphasis added).

...

HCPCS Codes

...

E0766 ELECTRICAL STIMULATION DEVICE USED FOR CANCER TREATMENT, INCLUDES ALL ACCESSORIES, ANY TYPE

...

THE National Comprehensive Cancer Network (NCCN) has updated its Clinical Practice Guidelines in Oncology for Central Nervous System Cancers (NCCN Guidelines®) to recommend alternating electric field therapy (also known as tumor-treating fields, Optune) in combination with temozolomide as a category 1 treatment for patients with newly diagnosed glioblastoma (<https://www.nccn.org>).

Analysis

The QIC denied the claim at issue finding that LCD L34823 stated that TTFT (E0766) is denied as not reasonable and necessary (Exh. 1, p. 4).

In her brief and at the hearing, Bridget Noonan argued that Glioblastoma is the most common but rare form of primary brain cancer that is highly aggressive with a survival of approximately ten months from the diagnosis date. She noted that Optune is durable medical equipment that delivers alternating electric fields or Tumor Treating Fields to the brain which slows the replication of cancer cells or stops their growth altogether. She emphasized that Optune is FDA approved for recurrent and newly diagnosed glioblastoma multiforme (GBM) brain tumors; that numerous peer-reviewed published studies have demonstrated the safety and efficacy of the Optune system and TTFT generally; and that Optune is incorporated in the NCCN guidelines (considered the gold standard for oncology management) for treatment of recurrent and newly-diagnosed GBM in combination with temozolomide. In addition, she pointed out that the Optune system has been certified at more than 800 cancer treatment centers, and has been prescribed by over 1200 physicians in 50 states, the District of Columbia, and Puerto Rico, for over 7200 patients. She argued that “[v]irtually every major payer in the United States covers the Optune system for individuals diagnosed with a glioblastoma. These payers include, among others, Highmark, Aetna, Anthem, Humana, Kaiser, UnitedHealthcare, Cigna, Harvard Pilgrim, Geisinger, HealthPartners, and several Blue Cross plans.” She further asserted that the LCD on its face does not reflect the current peer-reviewed literature, consensus of experts, the widespread adoption, and is currently the subject of a reconsideration request based on its deficiencies. She also contended that DMAC medical directors have indicated the antiquated LCD does not apply to newly diagnosed glioblastoma and thus should not be used to preclude coverage (Testimony and Exh. 5, pp. 5-8).

Mr. Parks testified that the Appellant was newly diagnosed with GBM in April 2018 and underwent the standard course of treatment, surgery, chemotherapy, and radiation, which ended in June 2018. The Appellant was started on Optune TTFT in August 2018 and subsequently her MRI scans were stable.

Dr. Carr testified that currently Humana provides coverage for Optune TTFT for commercial plan members, but that Humana does not provide coverage for Optune TTFT to Medicare enrollees based on LCD L34823. Dr. Carr asserted that while the LCD is under reconsideration, it is still in effect and must be followed by the MAO.

Application of LCD L34823

As noted above, ALJs are not bound by LCDs, LMRPs, or CMS program guidance such as program memoranda and manual instructions, but must give substantial deference to these policies if they are applicable to a particular case.

In the appeal at issue the Medicare Contractor, CGS, has stated that the cited LCD does not address coverage for newly diagnosed GBM – the Beneficiary’s diagnosis. Further, the MAC stated that the Appellant had made a “valid request” for consideration of newly diagnosed GBM.

The MAC further stated that the review process would be completed by September 18, 2018. At the hearing, the Appellant's Attorney, Ms. Noonan, stated that the reconsideration has not yet been completed, but that when it is completed, it would be retroactive to the date of the request, June 20, 2018.

Medical Effectiveness

The Optune®, formerly the NovoTTF-100A System, (Novocure, Portsmouth NH) was approved by the FDA in April 2011, as a novel device to treat adults age 22 years or older with GBM that recurs or progresses after receiving chemotherapy and radiation therapy. A supplemental FDA premarket approval was received in October 2015 for Optune™ with Temozolomide in adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy. For newly diagnosed GBM, Optune is not intended to be used as a substitute for standard treatments but rather as an adjunct therapy (<https://www.fda.gov/MedicalDevices/default.htm>).

Several major insurance carriers cover TTFT for GBM. For example, United Healthcare Electronic Tumor Treatment Field Therapy Policy, Effective Date: November 1, 2018 states in part:

The use of FDA approved devices to generate electric TTF is proven and medically necessary following radiologically-confirmed recurrence of GBM in the supratentorial region of the brain after initial chemotherapy and when ALL of the following criteria are met:

- ☐ The device is used as a monotherapy
- ☐ Individual has a KPS score of ≥ 60 ; and
- ☐ Individual or caregiver has been trained and is willing and able to apply the device daily; and
- ☐ Individual is willing to wear the device at least 18 hours daily.

When all of the above criteria are met for either newly diagnosed or recurrent GBM, an initial 3 months of electric TTF therapy will be approved.
<https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medical-drug/electric-tumor-treatment-field-therapy.pdf>

The Aetna Insurance Clinical Policy Bulletin states in part:

Aetna considers devices to generate electric tumor treatment fields (ETTF) and temozolomide medically necessary for persons with histologically confirmed glioblastoma (World Health Organization grade IV astrocytoma), after histologically or radiologically confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. (Note: For recurrent glioblastoma, treatment until disease progression is considered medically necessary).

Aetna considers combination of devices to generate ETTF and temozolomide medically necessary as adjunctive treatment of newly-diagnosed histologically

confirmed supratentorial glioblastoma following standard treatments that include surgery, chemotherapy, and radiation therapy.

On October 5, 2015, the FDA approved an expanded indication for the Optune device (using alternating electrical fields called “tumor treatment fields” [TT Fields]) to treat patients with newly-diagnosed GBM. It is administered along with temozolomide (TMZ) following standard treatments that include surgery, chemotherapy, and radiation therapy. In the clinical study used to support the expanded indication, patients treated with the device and TMZ lived on average 3 months longer than those treated with the drug alone. Optune was initially approved in 2011 to treat patients with GBM that recurred or progressed after chemotherapy. With this expanded indication, Optune can be used as part of a standard treatment for GBM before the disease progresses. For newly diagnosed GBM, Optune is not intended to be used as a substitute for standard treatments, but rather as an adjunct therapy. The device is portable and can be powered with batteries or plugged into an electrical outlet. Patients can use the device at home or work, allowing them to continue their normal daily activities.

The FDA based its approval of the expanded indication of the Optune device on results from a clinical trial involving 695 patients newly diagnosed with GBM that compared those who used Optune with TMZ to those receiving TMZ alone. Patients who used the device along with TMZ lived, on average, about 7 months with no disease progression compared to 4 months for those who had the drug alone. The Optune plus TMZ group survived for an average of 19.4 months after diagnosis compared to 16.6 months for those who were treated with only TMZ. The most common side effect experienced with Optune was skin irritation. Clinical trial participants also experienced a slightly higher incidence of neurological side effects, including convulsions and headaches, compared to subjects receiving TMZ alone. Patients should not use the Optune system if they have an active implanted medical device or a skull defect, have an underlying skin condition involving the scalp or have a known sensitivity to conductive hydrogels, such as those used on electrocardiogram stickers.

The Appellant noted several peer review studies including Effect of Tumor-Treating Fields Plus Maintenance Temozolomide vs Maintenance Temozolomide Alone on Survival in Patients With Glioblastoma: A Randomized Clinical Trial. Roger Stupp, MD et al JAMA 2017 at 2306-2316.

In the final analysis of this randomized phase 3 trial, the addition of the TT Fields treatment to standard temozolomide maintenance therapy, compared with standard temozolomide maintenance therapy alone, resulted in increased progression-free survival and overall survival in patients with newly diagnosed glioblastoma. After a median follow-up of 40 months, the addition of TT Fields to temozolomide, compared with temozolomide alone, resulted in longer median progression-free survival from the time of randomization, 6.7 months vs

4.0 months and longer median overall survival from randomization, 20.9 months vs 16.0 months, respectively (Exh. 5 CD).

In the appeal at issue, the Appellant was diagnosed with new GBM in April 2018. GBM is a rare, aggressive form of cancer with severely limited treatment options. The Appellant was treated with surgery, radiation, and chemotherapy. Her physician recommended TTFT, which she started receiving in August 2018.

Based on the arguments and evidence presented, I decline to apply the current LCD to the appeal at issue because the policy is not applicable to the appeal at issue. Specifically, LCD L34823 does not address newly diagnosed GBM, the Beneficiary's condition. Additionally, I find that the Appellant has submitted ample evidence to support a favorable decision in this appeal based on the peer-reviewed literature, FDA approval, and overwhelming current acceptance in the medical community for the Optune system as a treatment option for recurrent and newly diagnosed glioblastoma. Thus, I find that Humana is not limited in its approval of the TTFT for its commercial enrollees only and should approve the TTFT request for Medicare enrollees as well.

Conclusion of Law

Pursuant to the provisions of Title XVIII of the Act and implementing regulations, the Appellant's request for pre-authorization should have been approved. The MAO is required to provide coverage for Optune TTFT provided to the Appellant and billed as electrical stimulation device used for cancer treatment (E0766).

Order

The decision is **FAVORABLE** for the Appellant the claim in accordance with this decision.

. The Contractor is ordered to process

SO ORDERED.

Dated: MAR 07 2019


Marilyn Mann Faulkner
U.S. Administrative Law Judge

June 07, 2019

**PARRISH LAW OFFICES
788 WASHINGTON RD.
PITTSBURGH, PA 15228**

Medicare Reconsideration Decision

RE:

Beneficiary: D. Christenson
Med ID#: *****QP33
Appellant: D. Christenson

Dear D. Parrish:

This letter is to inform you of the decision on your Medicare Appeal. An appeal is a new and independent review of a claim. You are receiving this letter because you requested an appeal for the services shown under the Appeal Details section.

The appeal decision is UNFAVORABLE. Our decision is that Medicare will make no additional payment. More information on the decision is provided on the next pages. You are not required to take any action.

If you disagree with the decision, you may appeal to an Administrative Law Judge (ALJ). You must file your appeal, in writing, within 60 days of receipt of this letter. For more information on how to appeal, see the page entitled "Important Information About Your Appeal Rights." The amount still in dispute is estimated to be equal to or over \$160.00. However, the ALJ will determine if your appeal case meets the \$160.00 amount in controversy requirement for an ALJ hearing.

If this appeal is partially favorable or unfavorable, and it originated from an overpayment, the Medicare Administrative Contractor (MAC) is responsible for processing this determination in accordance with standard Medicare methodologies. Any outstanding debts, prior coverage, and prior reimbursement will be taken into account when processing this decision. The MAC will issue a

**Contact
Information**

If you have questions, write or call:

***C2C Innovative
Solutions, Inc.***
QIC DME
P.O. Box 44163
Jacksonville, FL
32231-4163

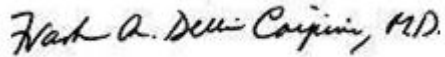
Telephone:
904-224-7433

Who we are:
We are a Qualified Independent Contractor (QIC). Medicare has contracted with us to review your file and make an independent decision.

demand letter containing information regarding the collection process, interest accrual, and requesting an extended repayment schedule (ERS).

A copy of this letter was also sent to the parties shown below. C2C Innovative Solutions, Inc. was contracted by Medicare to review your appeal. For more information on how to appeal, see the page titled "Important Information About Your Appeal Rights."

Sincerely,

A handwritten signature in black ink that reads "Frank A. Delli Carpini, M.D.".

Frank A. Delli Carpini, M.D.
Medical Director

CC: D. Christenson
Novocure Inc

Summary of Facts

The service(s) shown below were submitted for payment to CGS Administrators . The explanation of the decision was released in a Medicare Summary Notice to the beneficiary and a Remittance Advice to the provider of service. A request for a Redetermination appeal was submitted to the Medicare contractor. On March 11, 2019, CGS Administrators completed the appeal, and sent notice of the decision to the appropriate parties. On April 22, 2019, we received a QIC Reconsideration request for the services referenced in the “Appeal Details” section. Information and records reviewed by the QIC in this case included:

- Refer to Explanation of Decision for Key Documents

Decision

A panel of clinical experts consisting of a physician and a licensed health care professional reviewed the claim(s).

The decision on your appeal is shown below:

Medicare Coverage	Claim Number (ICN)	Procedure /Date of Service
Non-covered	18310809384000	E0766: Elec Stim Cancer Treatment - (11/03/18)
Non-covered	18338812665000	E0766: Elec Stim Cancer Treatment - (12/03/18)
Non-covered	19007808841000	E0766: Elec Stim Cancer Treatment - (01/03/19)

We have determined that the provider is responsible for the denied charges.

Explanation of the Decision

Claim Number:18310809384000

Claims for tumor treatment field therapy (TTFT) (E0766) for D. Christenson (Beneficiary or Appellant) were submitted by Novocure, Inc. (Novocure) for payment to CGS Administrators, LLC (CGS) the Durable Medical Equipment Medicare Administrative Contractor (DME MAC). The claims were denied with a finding that Medicare guidelines were not met.

On February 21, 2019, Novocure submitted a Redetermination Request to the DME MAC. On March 11, 2019, the DME MAC issued an unfavorable Redetermination Decision.

On April 22, 2019, C2C Innovative Solutions, Inc. (C2C), the DME Qualified Independent Contractor (QIC) received a Reconsideration Request dated April 16, 2019, from Debra M. Parrish, Esq. of Parrish Law Offices (also referred to as Appellant).

Key records contained in this case include:

DME MAC Redetermination Request dated February 21, 2019
DME MAC Redetermination Decision Letter dated March 11, 2019
Reconsideration Request dated April 16, 2019
Appointment of Representative (AOR) Form dated February 5, 2019
DME MAC Medical Directors Letter dated August 7, 2018
ALJ Decisions
National Comprehensive Cancer Network (NCCN) Guidelines
Centers for Medicare and Medicaid Services (CMS) Correspondence to Novocure
Clinical Studies
Food and Drug Administration Approvals
Invoice
Physician Order/Prescription
Physician Progress Notes
Diagnostic Results
Delivery Confirmation

Laws, Regulations, and Policy

For any item or service to be covered by Medicare, it must fall into a defined Medicare benefit category, it must not be statutorily excluded, it must be reasonable and necessary under § 1862(a)(1)(A) of the Social Security Act (SSA), and it must meet other Medicare program requirements for payment. Sections 414.200 through 414.232 of 42 the Code of Federal Regulations (CFR) cover payment for durable medical equipment and prosthetic and orthotic devices. The CMS Internet Only Manual (IOM), Medicare National Coverage Determinations (NCD) Manual, Publication (Pub.) 100-03, includes NCDs that pertain to certain Durable Medical Equipment, Prosthetics/Orthotics, and Supplies (DMEPOS) items. The Medicare Claims Processing Manual, Pub. 100-04, Chapter 20, instructs on billing and payment for DMEPOS. The Medicare Program Integrity Manual (PIM), Pub. 100-08, Chapter 5, provides guidance on medical review. The manuals are based upon the above cited law and regulations. DME MACs publish Local Coverage Determinations (LCDs) and related Policy Articles. The LCDs address the criteria for "reasonable and necessary," based on SSA § 1862(a)(1)(A). The articles encompass the non-medical necessity coverage and payment rules.

Reasonable and Medically Necessary

(a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—

(1)(A) which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, [SSA § 1862 (a)(1)(A)]

Authority of the QIC

With regard to authority of the QIC, 42 CFR § 405.968(b) provides:

(1) National coverage determinations (NCDs), CMS Rulings, and applicable laws and regulations are binding on the QIC.

(2) QICs are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but give substantial deference to these policies if they are applicable to a particular case. A QIC may decline to follow a policy, if the QIC determines, either at a party's request or at its own discretion, that the policy does not apply to the facts of the particular case.

(3) If a QIC declines to follow a policy in a particular case, the QIC's reconsideration explains the reasons why the policy was not followed.

(4) A QIC's decision to decline to follow a policy under this section applies only to the specific claim being reconsidered and does not have precedential effect.

(5) A QIC may raise and develop new issues that are relevant to the claims in a particular case provided that the contractor rendered a redetermination with respect to the claims. [42 CFR § 405.968(b)]

CMS Rulings

CMS Rulings are published under the authority of the Administrator of CMS. They are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS. [42 CFR §§ 401.108(c) and 405.1063(b)]

Definition – Contractor

Contractor means a carrier (including a Durable Medical Equipment Regional Carrier), or a fiscal intermediary (including a Regional Home Health Intermediary) that has jurisdiction for the LCD at issue. [42 CFR § 426.110]

LCD and NCD Reviews and Individual Claim Appeals

LCD and NCD reviews are distinct from the claims appeal processes set forth in part 405, subparts G and H; part 417, subpart Q; and part 422, subpart M of this chapter. [42 CFR § 426.310]

New LCD Request Requirements

Contractors [as defined in 42 CFR § 426.110] shall consider New LCD Requests to be a complete, formal request if the following are met:

- The request is in writing and can be sent to the MAC via e-mail, facsimile or written letter;
- The request clearly identifies the statutorily-defined Medicare benefit category to which the requestor believes the item or service falls under and provides a rationale justifying the assignment;

- The request shall identify the language that the requestor wants in an LCD;
- The request shall include a justification supported by peer-reviewed evidence. Full copies of published evidence to be considered shall be included and failure to include same invalidates the request;
- The request shall include information that addresses the relevance, usefulness, clinical health outcomes, or the medical benefits of the item or service; and
- The request shall include information that fully explains the design, purpose, and/or method, as appropriate, of using the item or service for which the request is made.

The MAC will review materials received within 60 calendar days upon receipt and determine whether the request is complete or incomplete. If the request is incomplete, the contractor shall respond, in writing, to the requestor explaining why the request was incomplete. If the request is complete, the MAC shall follow the process outlined in chapter 13 of Pub.100-08. A valid request response does not convey that a determination has been made whether or not the item or service will be covered or non-covered under 1862 (a)(1)(A) of the Act. The response to the requestor that the request is valid is simply an acknowledgement by the MAC of the receipt of a complete, valid request. [CMS IOM, Pub.100-08, PIM, Chapter 13, § 13.2.2.3]

LCD Reconsideration Process

The LCD reconsideration process is a mechanism by which a beneficiary or stakeholder (including a medical professional society or physician) in the MAC's jurisdiction can request a revision to an LCD. The LCD reconsideration process differs from an initial request for an LCD in that it is available only for final effective LCDs. The whole LCD or any provision of the LCD may be reconsidered. In addition, MACs have the discretion to revise or retire their LCDs at any time on their own initiative. [CMS IOM, Pub.100-08, PIM, Chapter 13, § 13.3]

Valid LCD Reconsideration Request Requirements

The requirements related to a valid LCD Reconsideration Request are as follows:

MACs shall consider all LCD reconsideration requests from:

- Beneficiaries residing or receiving care in a contractor's jurisdiction; and
- Providers doing business in a contractor's jurisdiction.
- Any interested party doing business in a contractor's jurisdiction.

MACs should only accept reconsideration requests for LCDs published as an effective final. Requests shall not be accepted for other documents including:

- National Coverage Determinations (NCDs);
- Coverage provisions in interpretive manuals;

- Proposed LCDs;
- Template LCDs, unless or until they are adopted and in effect by the contractor;
- Retired LCDs;
- Individual claim determinations
- Bulletins, articles, training materials; and
- Any instance in which no LCD exists, i.e., requests for development of an LCD.

If modification of the LCD would conflict with an NCD, the request would not be valid. The MAC should refer the requestor to the NCD reconsideration process. [CMS IOM, Pub.100-08, PIM, Chapter 13, § 13.3.2]

Reasonable and Necessary Provisions in LCDs

An item or service may be covered by a contractor LCD if:

- It is reasonable and necessary under 1862(a)(1)(A) of The Act. Only reasonable and necessary provisions are considered part of the LCD.

Reasonable and Necessary

Contractors [as defined in 42 CFR § 426.110] shall determine and describe in the LCD the circumstances under which the item or service is reasonable and necessary under 1862(a)(1)(A). Contractors shall determine if evidence exists to consider an item or service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:

Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;

Furnished in a setting appropriate to the patient's medical needs and condition;

Ordered and furnished by qualified personnel;

One that meets, but does not exceed, the patient's medical need; and

At least as beneficial as an existing and available medically appropriate alternative.
[CMS IOM, Pub.100-08, PIM, Chapter 13, § 13.5.4]

LCD L34823

LCD L34823 provides that TTFT will be denied as not reasonable and necessary. [LCD L34823 and Policy Article A52711]

Analysis

As noted above, this matter pertains to a denial of payment of claims for TTFT. Novocure disputed the denial and requested a Redetermination. The DME MAC issued an unfavorable Redetermination Decision. The DME MAC did not allow payment because the LCD states TTFT (E0766) is not reasonable and necessary. The Appellant has now requested a Reconsideration. At issue is payment for TTFT (E0766).

Please note the information obtained from the DME MAC, Novocure, and the Appellant was utilized in this Reconsideration Review. Documentation was evaluated to determine issues such as whether, in conjunction with other credible documentation, the service in question was actually provided or was provided as billed. The responsibilities of the QIC include rendering a decision only on the coverage or payment issues raised by the review request. The QIC may deny or reduce payment if it is believed the item or service at issue was not rendered or not rendered as billed. The QIC made a decision in this case based on whether the service was documented, appropriately ordered and delivered, and medically reasonable and necessary. The findings of this review are summarized below.

Appellant has set forth several arguments in the Reconsideration Request. Ms. Parrish, on behalf of the Beneficiary, opines that published literature supports the effectiveness of the device. In addition, she states the DME MAC Medical Directors have issued a statement indicating they do not interpret that the LCD applies to patients with newly diagnosed glioblastoma. Lastly, Ms. Parrish indicates the device is incorporated in the NCCN guidelines with a Category One designation.

The QIC has reviewed the correspondence Novocure received from CMS. The QIC finds the designation of an item as DME, is not an expression of coverage. In this instance, while the NovoTTF-100A System has been classified as DME, the LCD is clear in that TTFT will be denied as not reasonable and necessary.

The QIC has also reviewed the letter from the DME MAC Medical Directors and LCD L34823. Appellant interprets the August 7, 2018, letter from the DME MAC Medical Directors to indicate that the LCD does not apply to newly diagnosed glioblastoma. Review of the LCD indicates that the LCD is silent on the type of glioblastoma and does not differentiate between the newly diagnosed and recurrent glioblastoma. The LCD states that TTFT will be denied as not reasonable and necessary. The letter from the DME Medical Directors does indicate that they accepted a Reconsideration Request to consider coverage of TTFT for newly diagnosed glioblastoma. The QIC has reviewed Chapter 13 of the PIM with respect to creation of new LCDs and the Reconsideration process for changes to an existing LCD. The PIM, in pertinent part, details the following:

The development process for the new LCDs is set forth in the Medicare PIM. The CMS IOM, Pub. 100-08, PIM, Chapter 13, § 13.3 also details the process for a beneficiary or stakeholder to request a revision to an LCD, which is called the LCD Reconsideration Process. This Reconsideration Process strictly relates to potential revisions to an LCD and is separate and apart from the claims appeal process as set forth in 42 CFR § 426.310. The CMS IOM, Pub. 100-08, PIM, Chapter 13, § 13.2.2.3 states that new LCD requests will be reviewed by the MAC within 60 days of receipt of all materials and determined whether the request is complete or incomplete. If the request is incomplete, the contractor shall respond, in writing, to the requestor explaining why the request was incomplete. If the request is complete, the MAC shall follow the process outlined in Chapter 13 of the PIM. A valid request response does not convey that a determination has been made whether the item or service will be covered or non-covered under SSA § 1862 (a)(1)(A). The response to the requestor that the request is valid is simply an acknowledgement by the MAC of the receipt of a complete, valid request.

The CMS IOM, Pub. 100-08, PIM, Chapter 13, § 13.3.2 details that MACs shall consider all LCD reconsideration requests from: Beneficiaries residing or receiving care in a contractor's jurisdiction; and Providers doing business in a contractor's jurisdiction; and Any interested party doing business in a contractor's jurisdiction. MACs should only accept Reconsideration Requests for finalized LCDs that are effective and published. Requests shall not be accepted for other documents including: NCDs; Coverage provisions in interpretive manuals; Proposed LCDs; Template LCDs, unless or until they are adopted and in effect by the contractor; Retired LCDs; Individual claim determination; Bulletins, articles, training materials; and Any instance in which no LCD exists, i.e., requests for development of an LCD. If modification of the LCD would conflict with an NCD, the request would not be valid. The MAC should refer the requestor to the NCD reconsideration process. Requests shall be submitted in writing and shall identify the language that the requestor wants added to or deleted from an LCD. Requests shall include a justification supported by new evidence, which may materially affect the LCD's content or basis. Copies of published evidence shall be included. Any request for LCD reconsideration that, after MAC review, is determined to not meet these criteria is invalid. The CMS IOM, Pub. 100-08, PIM, Chapter 13, § 13.5.4 provides that an item or service may be covered by a contractor LCD if: it is reasonable and necessary under § 1862(a)(1)(A) of the SSA. Only reasonable and necessary provisions are considered part of the LCD. Contractors, as defined in 42 CFR § 426.110, shall determine and describe in the LCD the circumstances under which the item or service is reasonable and necessary under § 1862(a)(1)(A). Contractors shall determine if evidence exist to consider an item or service to be reasonable and necessary if the contractor determines that the service is: Safe and effective; Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is: furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member; Furnished in a setting appropriate to the patient's medical needs and condition; Ordered and furnished by qualified personnel; One that meets, but does not exceed, the patient's medical need; and At least as beneficial as an existing and available medically appropriate alternative.

The CMS IOM, Pub. 100-08, PIM, Chapter 13, § 13.5.4 further details that Contractor LCDs shall be based on the strongest evidence available. The extent and quality of supporting evidence is key to defending challenges to LCDs. The initial action in gathering evidence to support LCDs shall always be a search of published scientific literature for any available evidence pertaining to the item or service in question. In order of preference, LCDs should be based on: Published authoritative evidence derived

from definitive randomized clinical trials or other definitive studies, and general acceptance by the medical community (standard of practice), as supported by sound medical evidence based on: scientific data or research studies published in peer-reviewed medical journals; Consensus of expert medical opinion (i.e., recognized authorities in the field); or Medical opinion derived from consultations with medical associations or other health care experts.

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

LCDs that challenge the standard of practice in a community and specify that an item or service is never reasonable and necessary shall be based on sufficient evidence to convincingly refute evidence presented in support of coverage.

The QIC understands that the DME MACs have found a request for reconsideration for newly diagnosed glioblastoma as valid. However, the DME MACs have not issued a new LCD providing coverage for newly diagnosed glioblastoma. The acceptance of a reconsideration request as valid by the DME MAC is not in and of itself evidence of the DME MAC's intent to allow coverage. It is merely an acknowledgement that the request for reconsideration was deemed valid, as set forth in the PIM.

According to the documentation submitted, the TTFT is being used to treat the Beneficiary's diagnosis of glioblastoma. The Appellant argues that the device is reasonable and necessary and published literature supports the effectiveness of the device. However, the QIC has reviewed the NCCN guidelines and the medical literature and finds the medical documentation of the efficacy of this device is not within the usual scope and breath of current medical literature with peer acknowledgment and review. More specifically, the QIC has reviewed the peer reviewed and evidence based literature relative to clinical trials for TTFT and found the literature and clinical trials to be limited in number and the clinical trials not non-biased; that is, the clinical trials were not independent, but funded by Novocure, Inc. The device is considered to be within the non-covered category for treatment of this condition as per the LCD.

The QIC has also reviewed LCD L34823, as noted above. The LCD for TTFT (L34823) states that for any item to be covered by Medicare, it must: 1) Be eligible for a defined Medicare benefit category; 2) Be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member; and 3) Meet all other applicable Medicare statutory and regulatory requirements. The purpose of an LCD is to provide information regarding reasonable and necessary criteria based on SSA § 1862(a)(1)(A) provisions. The LCD clearly and unequivocally states that TTFT (E0766) will be denied as not reasonable and necessary.

As noted above, the QIC understands that the DME MACs have found a request for reconsideration for newly diagnosed glioblastoma as valid. However, the DME MACs have not issued a new LCD providing coverage for newly diagnosed glioblastoma. The acceptance of a reconsideration request as valid by the DME MAC is not evidence of the DME MAC's intent to allow coverage. It is an acknowledgement that the request for reconsideration was deemed valid, as set forth in the PIM. The LCD L34823 details that TTFT (E0766) will be denied as not reasonable and necessary. This LCD

remains in effect until such time the DME MAC retires the non-coverage LCD or a new LCD becomes effective. Therefore, in accordance with the aforementioned LCD, the claim for TTFT services is determined to be not reasonable or necessary.

Based on the available documentation, the requirements of the LCD and PIM have not been met. Therefore, the claims cannot receive reimbursement.

Conclusion

The decision of the QIC is unfavorable. After careful consideration, the QIC finds that the services did not meet the requirements to be considered medically reasonable and necessary in the treatment of the patients, in tandem with the application of Medicare guidelines and the Medicare Local Coverage policies.

Claim Number:18338812665000

Please refer to ICN 18310809384000 for the complete decision for this claim.

Claim Number:19007808841000

Please refer to ICN 18310809384000 for the complete decision for this claim.

Who is Responsible for the Bill?

When services are denied as not medically reasonable and necessary under the Medicare program, we must also determine if the provider or beneficiary is liable for payment. Section 1879(a)-(g) of the SSA, also referred to as "the limitation on liability provision," specifies how to arrive at this decision. Medicare regulations, 42 CFR 424, require providers to be familiar with Medicare rules and regulations. In addition, 42 CFR 411.406 provides criteria for determining when a provider is responsible for payment for the services considered not reasonable and necessary. This regulation states that providers are presumed to have knowledge of published Medicare coverage rules and regulations, Centers for Medicare and Medicaid Services (CMS) Rulings, Medicare coverage policies in CGS Administrators bulletins or websites, and acceptable standards within the local community. We find that Novocure is liable for the denied charges. The record does not support that the beneficiary was notified in advance that Medicare would likely deny payment.

Other Important Information

If you appeal this decision the Administrative Law Judge (ALJ) will not consider new evidence unless you show good cause for not presenting the evidence to the QIC. This requirement does not apply to beneficiaries, unless a provider or supplier represents the beneficiary.

For information on how to appeal this decision, refer to the page titled "Important Information About Your Appeal Rights." If you need more information or have any questions, please call 1-800-Medicare (1-800-633-4227) [TTY/TDD: 1-800-486-2048] or the phone number listed on page one.

You can receive copies of statutes, regulations, policies, and/or manual instructions we used to arrive at this decision. For instructions on how to do this, please see ‘Other Important Information’ on the page entitled “Important Information About Your Appeal Rights.” The request must be submitted in writing to this office.

**Medicare Appeal
Number:**

1-8486340738

Appeal Details

Beneficiary	D. Christenson		
Provider	Novocure Inc.		
Claim Number	Date of Service	Procedure	Medicare QIC Decision
18310809384000	11/03/18	E0766: Elec Stim Cancer Treatment	Unfavorable
18338812665000	12/03/18	E0766: Elec Stim Cancer Treatment	Unfavorable
19007808841000	01/03/19	E0766: Elec Stim Cancer Treatment	Unfavorable

THIS IS NOT A BILL – Keep this letter or a copy for your records.

IMPORTANT INFORMATION ABOUT YOUR APPEAL RIGHTS

Your Right to Appeal this Decision

If you do not agree with this decision, you may appeal the decision to an Administrative Law Judge (ALJ) at the Office of Medicare Hearings and Appeals (OMHA). The ALJ will review the decision to determine whether it is correct.

As of January 1, 2018, you must have \$160.00 in dispute to appeal to an ALJ. A claim can be combined ("aggregated") with others to reach this amount if: (1) the other claims have also been decided or dismissed by a QIC; (2) all of the claims are listed on your request for review; (3) your request for review is filed within 60 days of receipt of all of the Qualified Independent Contractor (QIC) decisions being appealed; and (4) you explain why you believe the claims involve similar or related services. You can find more information about your right to an ALJ review of a QIC decision at www.hhs.gov/omha or by calling 1-855-556-8475. This is a toll free call.

How to Appeal

To exercise your right to appeal, you must file a written request for an ALJ review within **60 days** of receiving this letter. If your request for review is being filed late, you must explain why your request is being filed late. After you file an appeal, you may check your appeal's status via the OMHA website at www.hhs.gov/omha (click on Appeal Status Lookup).

When preparing your request for review, please use **Form OMHA-100**, available at:

www.hhs.gov/omha/forms/index.html

If you do not use the form, your request for review must include the following:

1. The Beneficiary's name, address, and Medicare health insurance claim number;
2. The name and address of the person appealing, if the person is not the beneficiary;
3. The representative's name and address, if any;
4. The Medicare appeal number listed on the front page of this Reconsideration notice;
5. The dates of service for the claims at issue;
6. The reasons why you disagree with the QIC's decision; and
7. A statement of any additional evidence to be submitted and the date it will be submitted.

You must send a copy of the request for ALJ review to the other parties who received a copy of this decision (for example, the beneficiary or provider/supplier). Please **do not** send a copy of your review request to the QIC that issued this decision or to the Medicare Administrative Contractor (MAC) that issued the Redetermination.

Mail your review request to (tracked mail is suggested):

HHS OMHA Central Operations
200 Public Square, Suite 1260
Cleveland, OH 44114-2316

OMHA processes Medicare **Beneficiary** appeals on a priority basis. If you are a Beneficiary or you represent a Beneficiary, mail your review request to:

HHS OMHA Central Operations
Attn: Beneficiary Mail Stop
200 Public Square, Suite 1260
Cleveland, OH 44114-2316

If you are a Beneficiary or represent a Beneficiary, you can also call the OMHA Beneficiary help line at 1-844-419-3358 for assistance. This is a toll free call. For more information on the OMHA Beneficiary prioritization program, including limitations for Beneficiaries represented by a provider/supplier, or a shared representative, visit the OMHA website at www.hhs.gov/omha or call the Beneficiary help line.

Who May File an Appeal

You or someone you name to act for you (your **appointed representative**) may file an appeal. You can name a relative, friend, advocate, attorney, doctor, or someone else to act for you.

If you want someone to act for you, you and your appointed representative must sign and date a statement naming that person to act for you and send it with your request for review. Call 1-800-MEDICARE (1-800-633-4227) to learn more about how to name a representative.

Help With Your Appeal

You can have a friend or someone else help you with your appeal. If you have any questions about payment denials or appeals, you can also contact your State Health Insurance Assistance Program (SHIP). For information on contacting your local SHIP, call 1-800-MEDICARE (1-800-633-4227).

Other Important Information

If you want copies of statutes, regulations, and/or policies we used to arrive at this dismissal, please write to us and attach a copy of this letter, at:

C2C Innovative Solutions, Inc.

A Medicare Contractor

P.O. Box 44163

Jacksonville FL 32231-4163

If you have questions, please call us at the phone number provided on the front of this notice.

Other Resources To Help You

1-800-MEDICARE (1-800-633-4227),
TTY/TDD: 1-800-486-2048

If you need large print or assistance, call 1-800-633-4227

~~excludeinsert~~**Nondiscrimination Notice** - The Centers for Medicare & Medicaid Services Centers for Medicare and Medicaid Services (CMS) doesn't exclude, deny benefits to, or otherwise discriminate against any person on the basis of race, color, national origin, disability, sex, or age. If you think you've been discriminated against or treated unfairly for any of these reasons, you can file a complaint with the Department of Health and Human Services, Office for Civil Rights by:

- Calling 1-800-368-1019. TTY users should call 1-800-537-7697.
- Visiting hhs.gov/ocr/civilrights/complaints.
- Writing: Office for Civil Rights, U.S. Department of Health and Human Services, 200 Independence Avenue SW, Room 509F, HHH Building, Washington, D.C. 20201

Notice of Availability of Auxiliary Aids & Services - We're committed to making our programs, benefits, services, facilities, information, and technology accessible in accordance with Sections 504 and 508 of the Rehabilitation Act of 1973. We'll take appropriate steps to make sure that people with disabilities, including people who are deaf, hard of hearing or blind, or who have low vision or other sensory limitations, have an equal opportunity to participate in our services, activities, programs, and other benefits. We provide various auxiliary aids and services to communicate with people with disabilities, including:

- Relay service — TTY users should call 1-877-486-2048.
- Alternate formats — This Medicare Reconsideration Notice is available in alternate formats, including large print, Braille, data CD and audio CD. To request your notice in an alternate format, call 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

Aviso sobre la discriminación - Los Centros de Servicios de Medicare y Medicaid (CMS) no excluye, niega beneficios o discrimina contra ninguna persona por motivos de raza, color, origen nacional, incapacidad, género o edad. Si cree que ha sido discriminado o tratado injustamente por cualquiera de estos motivos, puede presentar una queja ante el Departamento de Salud y Servicios Humanos, Oficina de Derechos Civiles:

- Llamando al 1-800-368-1019. Los usuarios de TTY deben llamar al 1-800-537-7697.
- Visitando hhs.gov/ocr/civilrights/complaints.
- Escribiendo a la: Oficina de Derechos Civiles del Departamento de Salud y Servicios Humanos 200 Independence Avenue, SW Room 509F, HHH Building Washington, D.C. 20201

Ayuda y servicios auxiliares para personas con incapacidades - Medicare está dedicado a ofrecerles a todos sus beneficiarios los programas, beneficios, servicios, dependencias, información y su tecnología, en cumplimiento con las Secciones 504 y 508 de la Ley de Rehabilitación del 1973. Medicare tomará las medidas necesarias para asegurarse de que las personas incapacitadas, entre los que se incluyen los que tiene problemas auditivos, son sordos, ciegos, tienen problemas visuales u otro tipo de limitaciones, tengan las mismas oportunidades de participar y aprovechar los programas y beneficios disponibles. Medicare ofrece varios servicios y ayuda para facilitar la comunicación con las personas incapacitadas incluyendo:

- Servicios de retransmisión de mensajes — Los usuarios de TTY deben llamar al 1-877-486-2048.
- Formatos alternativos — Los productos de Medicare, incluyendo esta reconsideración, están disponible en letra grande, versión digital, Braille y audio. Para ordenar su aviso en un formato alternativo, llame al 1-800-MEDICARE (1-800-633-4227). Los usuarios de TTY deben llamar al 1-877-486-2048.

ATTENTION: If you speak a language other than English, language assistance services, free of charge, are available to you. Call 1-800-MEDICARE (TTY: 1-877-486-2048).

(Arabic) العربية ملاحظة: إن كنت تتحدث لغة أخرى غير الانجليزية، فإن خدمات المساعدة اللغوية متوفرة لك بالمجان. اتصل بالرقم 1-800-MEDICARE (الهاتف النصي: 1-877-486-2048).

հայերեն (Armenian) ՈՒՇԱԴՐՈՒԹՅՈՒՆ՝ Եթե խոսում եք հայերեն, ապա ձեզ անվճար կարող են տրամադրվել լեզվական աջակցության ծառայություններ: Չանգահարեք 1-800-MEDICARE (TTY (հեռախոս)՝ 1-877-486-2048)

繁體中文 (Chinese) 注意: 如果您使用繁體中文, 您可以免費獲得語言援助服務。請致電 1-800-MEDICARE (TTY: 1-877-486-2048)。

فارسی (Farsi) توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 1-800-MEDICARE (TTY: 1-877-486-2048) تماس بگیرید.

Français (French) ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-MEDICARE (ATS : 1-877-486-2048).

Kreyòl Ayisyen (French Creole) ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 1-800-MEDICARE (TTY: 1-877-486-2048).

Deutsch (German) ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1-800-MEDICARE (TTY: 1-877-486-2048).

Italiano (Italian) ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 1-800-MEDICARE (TTY: 1-877-486-2048).

日本語 (Japanese)

注意事項：日本語を話される場合、無料の言語支援をご利用いただけます。1-800-MEDICARE (TTY:1-877-486-2048) まで、お電話にてご連絡ください。

한국어(Korean) 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1-800-MEDICARE (TTY: 1-877-486-2048) 번으로 전화해 주십시오.

Polski (Polish) UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1-800-MEDICARE (TTY: 1-877-486-2048).

Português (Portuguese) ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 1-800-MEDICARE (TTY: 1-877-486-2048).

Русский (Russian) ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1-800-MEDICARE (телетайп: 1-877-486-2048).

Español (Spanish) ATENCIÓN: Si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-800-MEDICARE (TTY: 1-877-486-2048).

Tagalog (Tagalog) PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1-800-MEDICARE (TTY: 1-877-486-2048).

Tiếng Việt (Vietnamese) CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-MEDICARE (TTY: 1-877-486-2048).

June 07, 2019

**NOVOCURE INC.
195 COMMERCE WAY
PORTSMOUTH, NH 03801-9999**

Medicare Reconsideration Decision

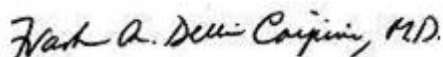
RE: Reconsideration Request
Reference attached chart for Appeal details

Dear Novocure Inc:

Based on Medicare guidelines, you are entitled to a copy of our decision. Refer to the attached information for a description of the services that were at issue as well as our decision.

This notice is an informational copy for your records.

Sincerely,



Frank A. Delli Carpini, M.D.
Medical Director

Enclosure: Reconsideration decision

**Contact
Information**

If you have
questions, write or
call:

***C2C Innovative
Solutions, Inc.***

QIC DME
P.O. Box 44163
Jacksonville, FL
32231-4163

Telephone:
904-224-7433

Who we are:
We are a Qualified
Independent
Contractor (QIC).
Medicare has
contracted with us to
review your file and
make an independent
decision.

Summary of Facts

The service(s) shown below were submitted for payment to CGS Administrators. The explanation of the decision was released in a Medicare Summary Notice to the beneficiary and a Remittance Advice to the provider of service. A request for a Redetermination appeal was submitted to the Medicare Administrative Contractor (MAC). On March 11, 2019, CGS Administrators completed the appeal and sent notice of the decision to the appropriate parties. On April 22, 2019, we received a QIC Reconsideration request for the services referenced in the "Appeal Details" section. Information and records reviewed by the QIC in this case included:

- Refer to Explanation of Decision for Key Documents

Decision

A panel of clinical experts consisting of a physician and a licensed health care professional reviewed the claim(s).

The decision on your appeal is shown below:

Medicare Coverage	Claim Number (ICN)	Procedure /Date of Service
Non-covered	18310809384000	E0766: Elec Stim Cancer Treatment - (11/03/18)
Non-covered	18338812665000	E0766: Elec Stim Cancer Treatment - (12/03/18)
Non-covered	19007808841000	E0766: Elec Stim Cancer Treatment - (01/03/19)

We have determined that the provider is responsible for the denied charges.

Explanation of the Decision

Claim Number: 18310809384000

Claims for tumor treatment field therapy (TTFT) (E0766) for D. Christenson (Beneficiary or Appellant) were submitted by Novocure, Inc. (Novocure) for payment to CGS Administrators, LLC (CGS) the Durable Medical Equipment Medicare Administrative Contractor (DME MAC). The claims were denied with a finding that Medicare guidelines were not met.

On February 21, 2019, Novocure submitted a Redetermination Request to the DME MAC. On March 11, 2019, the DME MAC issued an unfavorable Redetermination Decision.

On April 22, 2019, C2C Innovative Solutions, Inc. (C2C), the DME Qualified Independent Contractor (QIC) received a Reconsideration Request dated April 16, 2019, from Debra M. Parrish, Esq. of Parrish Law Offices (also referred to as Appellant).

Key records contained in this case include:

DME MAC Redetermination Request dated February 21, 2019
DME MAC Redetermination Decision Letter dated March 11, 2019
Reconsideration Request dated April 16, 2019
Appointment of Representative (AOR) Form dated February 5, 2019
DME MAC Medical Directors Letter dated August 7, 2018
ALJ Decisions
National Comprehensive Cancer Network (NCCN) Guidelines
Centers for Medicare and Medicaid Services (CMS) Correspondence to Novocure
Clinical Studies
Food and Drug Administration Approvals
Invoice
Physician Order/Prescription
Physician Progress Notes
Diagnostic Results
Delivery Confirmation

Laws, Regulations, and Policy

For any item or service to be covered by Medicare, it must fall into a defined Medicare benefit category, it must not be statutorily excluded, it must be reasonable and necessary under § 1862(a)(1)(A) of the Social Security Act (SSA), and it must meet other Medicare program requirements for payment. Sections 414.200 through 414.232 of 42 the Code of Federal Regulations (CFR) cover payment for durable medical equipment and prosthetic and orthotic devices. The CMS Internet Only Manual (IOM), Medicare National Coverage Determinations (NCD) Manual, Publication (Pub.) 100-03, includes NCDs that pertain to certain Durable Medical Equipment, Prosthetics/Orthotics, and Supplies (DMEPOS) items. The Medicare Claims Processing Manual, Pub. 100-04, Chapter 20, instructs on billing and payment for DMEPOS. The Medicare Program Integrity Manual (PIM), Pub. 100-08, Chapter 5, provides guidance on medical review. The manuals are based upon the above cited law and regulations. DME MACs publish Local Coverage Determinations (LCDs) and related Policy Articles. The LCDs address the criteria for "reasonable and necessary," based on SSA § 1862(a)(1)(A). The articles encompass the non-medical necessity coverage and payment rules.

Reasonable and Medically Necessary

(a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—

(1)(A) which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, [SSA § 1862 (a)(1)(A)]

Authority of the QIC

Revision Date

01272017

With regard to authority of the QIC, 42 CFR § 405.968(b) provides:

(1) National coverage determinations (NCDs), CMS Rulings, and applicable laws and regulations are binding on the QIC.

(2) QICs are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but give substantial deference to these policies if they are applicable to a particular case. A QIC may decline to follow a policy, if the QIC determines, either at a party's request or at its own discretion, that the policy does not apply to the facts of the particular case.

(3) If a QIC declines to follow a policy in a particular case, the QIC's reconsideration explains the reasons why the policy was not followed.

(4) A QIC's decision to decline to follow a policy under this section applies only to the specific claim being reconsidered and does not have precedential effect.

(5) A QIC may raise and develop new issues that are relevant to the claims in a particular case provided that the contractor rendered a redetermination with respect to the claims. [42 CFR § 405.968(b)]

CMS Rulings

CMS Rulings are published under the authority of the Administrator of CMS. They are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS. [42 CFR §§ 401.108(c) and 405.1063(b)]

Definition – Contractor

Contractor means a carrier (including a Durable Medical Equipment Regional Carrier), or a fiscal intermediary (including a Regional Home Health Intermediary) that has jurisdiction for the LCD at issue. [42 CFR § 426.110]

LCD and NCD Reviews and Individual Claim Appeals

LCD and NCD reviews are distinct from the claims appeal processes set forth in part 405, subparts G and H; part 417, subpart Q; and part 422, subpart M of this chapter. [42 CFR § 426.310]

New LCD Request Requirements

Contractors [as defined in 42 CFR § 426.110] shall consider New LCD Requests to be a complete, formal request if the following are met:

- The request is in writing and can be sent to the MAC via e-mail, facsimile or written letter;
- The request clearly identifies the statutorily-defined Medicare benefit category to which the requestor believes the item or service falls under and provides a rationale justifying the assignment;

- The request shall identify the language that the requestor wants in an LCD;
- The request shall include a justification supported by peer-reviewed evidence. Full copies of published evidence to be considered shall be included and failure to include same invalidates the request;
- The request shall include information that addresses the relevance, usefulness, clinical health outcomes, or the medical benefits of the item or service; and
- The request shall include information that fully explains the design, purpose, and/or method, as appropriate, of using the item or service for which the request is made.

The MAC will review materials received within 60 calendar days upon receipt and determine whether the request is complete or incomplete. If the request is incomplete, the contractor shall respond, in writing, to the requestor explaining why the request was incomplete. If the request is complete, the MAC shall follow the process outlined in chapter 13 of Pub.100-08. A valid request response does not convey that a determination has been made whether or not the item or service will be covered or non-covered under 1862 (a)(1)(A) of the Act. The response to the requestor that the request is valid is simply an acknowledgement by the MAC of the receipt of a complete, valid request. [CMS IOM, Pub.100-08, PIM, Chapter 13, § 13.2.2.3]

LCD Reconsideration Process

The LCD reconsideration process is a mechanism by which a beneficiary or stakeholder (including a medical professional society or physician) in the MAC's jurisdiction can request a revision to an LCD. The LCD reconsideration process differs from an initial request for an LCD in that it is available only for final effective LCDs. The whole LCD or any provision of the LCD may be reconsidered. In addition, MACs have the discretion to revise or retire their LCDs at any time on their own initiative. [CMS IOM, Pub.100-08, PIM, Chapter 13, § 13.3]

Valid LCD Reconsideration Request Requirements

The requirements related to a valid LCD Reconsideration Request are as follows:

MACs shall consider all LCD reconsideration requests from:

- Beneficiaries residing or receiving care in a contractor's jurisdiction; and
- Providers doing business in a contractor's jurisdiction.
- Any interested party doing business in a contractor's jurisdiction.

MACs should only accept reconsideration requests for LCDs published as an effective final. Requests shall not be accepted for other documents including:

- National Coverage Determinations (NCDs);
- Coverage provisions in interpretive manuals;

- Proposed LCDs;
- Template LCDs, unless or until they are adopted and in effect by the contractor;
- Retired LCDs;
- Individual claim determinations
- Bulletins, articles, training materials; and
- Any instance in which no LCD exists, i.e., requests for development of an LCD.

If modification of the LCD would conflict with an NCD, the request would not be valid. The MAC should refer the requestor to the NCD reconsideration process. [CMS IOM, Pub.100-08, PIM, Chapter 13, § 13.3.2]

Reasonable and Necessary Provisions in LCDs

An item or service may be covered by a contractor LCD if:

- It is reasonable and necessary under 1862(a)(1)(A) of The Act. Only reasonable and necessary provisions are considered part of the LCD.

Reasonable and Necessary

Contractors [as defined in 42 CFR § 426.110] shall determine and describe in the LCD the circumstances under which the item or service is reasonable and necessary under 1862(a)(1)(A). Contractors shall determine if evidence exists to consider an item or service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:

Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;

Furnished in a setting appropriate to the patient's medical needs and condition;

Ordered and furnished by qualified personnel;

One that meets, but does not exceed, the patient's medical need; and

Revision Date

01272017

At least as beneficial as an existing and available medically appropriate alternative.
[CMS IOM, Pub.100-08, PIM, Chapter 13, § 13.5.4]

LCD L34823

LCD L34823 provides that TTFT will be denied as not reasonable and necessary. [LCD L34823 and Policy Article A52711]

Analysis

As noted above, this matter pertains to a denial of payment of claims for TTFT. Novocure disputed the denial and requested a Redetermination. The DME MAC issued an unfavorable Redetermination Decision. The DME MAC did not allow payment because the LCD states TTFT (E0766) is not reasonable and necessary. The Appellant has now requested a Reconsideration. At issue is payment for TTFT (E0766).

Please note the information obtained from the DME MAC, Novocure, and the Appellant was utilized in this Reconsideration Review. Documentation was evaluated to determine issues such as whether, in conjunction with other credible documentation, the service in question was actually provided or was provided as billed. The responsibilities of the QIC include rendering a decision only on the coverage or payment issues raised by the review request. The QIC may deny or reduce payment if it is believed the item or service at issue was not rendered or not rendered as billed. The QIC made a decision in this case based on whether the service was documented, appropriately ordered and delivered, and medically reasonable and necessary. The findings of this review are summarized below.

Appellant has set forth several arguments in the Reconsideration Request. Ms. Parrish, on behalf of the Beneficiary, opines that published literature supports the effectiveness of the device. In addition, she states the DME MAC Medical Directors have issued a statement indicating they do not interpret that the LCD applies to patients with newly diagnosed glioblastoma. Lastly, Ms. Parrish indicates the device is incorporated in the NCCN guidelines with a Category One designation.

The QIC has reviewed the correspondence Novocure received from CMS. The QIC finds the designation of an item as DME, is not an expression of coverage. In this instance, while the NovoTTFT-100A System has been classified as DME, the LCD is clear in that TTFT will be denied as not reasonable and necessary.

The QIC has also reviewed the letter from the DME MAC Medical Directors and LCD L34823. Appellant interprets the August 7, 2018, letter from the DME MAC Medical Directors to indicate that the LCD does not apply to newly diagnosed glioblastoma. Review of the LCD indicates that the LCD is silent on the type of glioblastoma and does not differentiate between the newly diagnosed and recurrent glioblastoma. The LCD states that TTFT will be denied as not reasonable and necessary. The letter from the DME Medical Directors does indicate that they accepted a Reconsideration Request to consider coverage of TTFT for newly diagnosed glioblastoma. The QIC has reviewed Chapter 13 of the PIM with respect to creation of new LCDs and the Reconsideration process for changes to an existing LCD. The PIM, in pertinent part, details the following:

The development process for the new LCDs is set forth in the Medicare PIM. The CMS IOM, Pub. 100-08, PIM, Chapter 13, § 13.3 also details the process for a beneficiary or stakeholder to request a revision to an LCD, which is called the LCD Reconsideration Process. This Reconsideration Process strictly relates to potential revisions to an LCD and is separate and apart from the claims appeal process as set forth in 42 CFR § 426.310. The CMS IOM, Pub. 100-08, PIM, Chapter 13, § 13.2.2.3 states that new LCD requests will be reviewed by the MAC within 60 days of receipt of all materials and determined whether the request is complete or incomplete. If the request is incomplete, the contractor shall respond, in writing, to the requestor explaining why the request was incomplete. If the request is complete, the MAC shall follow the process outlined in Chapter 13 of the PIM. A valid request response does not convey that a determination has been made whether the item or service will be covered or non-covered under SSA § 1862 (a)(1)(A). The response to the requestor that the request is valid is simply an acknowledgement by the MAC of the receipt of a complete, valid request.

The CMS IOM, Pub. 100-08, PIM, Chapter 13, § 13.3.2 details that MACs shall consider all LCD reconsideration requests from: Beneficiaries residing or receiving care in a contractor's jurisdiction; and Providers doing business in a contractor's jurisdiction; and Any interested party doing business in a contractor's jurisdiction. MACs should only accept Reconsideration Requests for finalized LCDs that are effective and published. Requests shall not be accepted for other documents including: NCDs; Coverage provisions in interpretive manuals; Proposed LCDs; Template LCDs, unless or until they are adopted and in effect by the contractor; Retired LCDs; Individual claim determination; Bulletins, articles, training materials; and Any instance in which no LCD exists, i.e., requests for development of an LCD. If modification of the LCD would conflict with an NCD, the request would not be valid. The MAC should refer the requestor to the NCD reconsideration process. Requests shall be submitted in writing and shall identify the language that the requestor wants added to or deleted from an LCD. Requests shall include a justification supported by new evidence, which may materially affect the LCD's content or basis. Copies of published evidence shall be included. Any request for LCD reconsideration that, after MAC review, is determined to not meet these criteria is invalid. The CMS IOM, Pub. 100-08, PIM, Chapter 13, § 13.5.4 provides that an item or service may be covered by a contractor LCD if: it is reasonable and necessary under § 1862(a)(1)(A) of the SSA. Only reasonable and necessary provisions are considered part of the LCD. Contractors, as defined in 42 CFR § 426.110, shall determine and describe in the LCD the circumstances under which the item or service is reasonable and necessary under § 1862(a)(1)(A). Contractors shall determine if evidence exist to consider an item or service to be reasonable and necessary if the contractor determines that the service is: Safe and effective; Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is: furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member; Furnished in a setting appropriate to the patient's medical needs and condition; Ordered and furnished by qualified personnel; One that meets, but does not exceed, the patient's medical need; and At least as beneficial as an existing and available medically appropriate alternative.

The CMS IOM, Pub. 100-08, PIM, Chapter 13, § 13.5.4 further details that Contractor LCDs shall be based on the strongest evidence available. The extent and quality of supporting evidence is key to defending challenges to LCDs. The initial action in gathering evidence to support LCDs shall always be a search of published scientific literature for any available evidence pertaining to the item or service in question. In order of preference, LCDs should be based on: Published authoritative evidence derived

from definitive randomized clinical trials or other definitive studies, and general acceptance by the medical community (standard of practice), as supported by sound medical evidence based on: scientific data or research studies published in peer-reviewed medical journals; Consensus of expert medical opinion (i.e., recognized authorities in the field); or Medical opinion derived from consultations with medical associations or other health care experts.

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

LCDs that challenge the standard of practice in a community and specify that an item or service is never reasonable and necessary shall be based on sufficient evidence to convincingly refute evidence presented in support of coverage.

The QIC understands that the DME MACs have found a request for reconsideration for newly diagnosed glioblastoma as valid. However, the DME MACs have not issued a new LCD providing coverage for newly diagnosed glioblastoma. The acceptance of a reconsideration request as valid by the DME MAC is not in and of itself evidence of the DME MAC's intent to allow coverage. It is merely an acknowledgement that the request for reconsideration was deemed valid, as set forth in the PIM.

According to the documentation submitted, the TTFT is being used to treat the Beneficiary's diagnosis of glioblastoma. The Appellant argues that the device is reasonable and necessary and published literature supports the effectiveness of the device. However, the QIC has reviewed the NCCN guidelines and the medical literature and finds the medical documentation of the efficacy of this device is not within the usual scope and breath of current medical literature with peer acknowledgment and review. More specifically, the QIC has reviewed the peer reviewed and evidence based literature relative to clinical trials for TTFT and found the literature and clinical trials to be limited in number and the clinical trials not non-biased; that is, the clinical trials were not independent, but funded by Novocure, Inc. The device is considered to be within the non-covered category for treatment of this condition as per the LCD.

The QIC has also reviewed LCD L34823, as noted above. The LCD for TTFT (L34823) states that for any item to be covered by Medicare, it must: 1) Be eligible for a defined Medicare benefit category; 2) Be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member; and 3) Meet all other applicable Medicare statutory and regulatory requirements. The purpose of an LCD is to provide information regarding reasonable and necessary criteria based on SSA § 1862(a)(1)(A) provisions. The LCD clearly and unequivocally states that TTFT (E0766) will be denied as not reasonable and necessary.

As noted above, the QIC understands that the DME MACs have found a request for reconsideration for newly diagnosed glioblastoma as valid. However, the DME MACs have not issued a new LCD providing coverage for newly diagnosed glioblastoma. The acceptance of a reconsideration request as valid by the DME MAC is not evidence of the DME MAC's intent to allow coverage. It is an acknowledgement that the request for reconsideration was deemed valid, as set forth in the PIM. The LCD L34823 details that TTFT (E0766) will be denied as not reasonable and necessary. This LCD

remains in effect until such time the DME MAC retires the non-coverage LCD or a new LCD becomes effective. Therefore, in accordance with the aforementioned LCD, the claim for TTFT services is determined to be not reasonable or necessary.

Based on the available documentation, the requirements of the LCD and PIM have not been met. Therefore, the claims cannot receive reimbursement.

Conclusion

The decision of the QIC is unfavorable. After careful consideration, the QIC finds that the services did not meet the requirements to be considered medically reasonable and necessary in the treatment of the patients, in tandem with the application of Medicare guidelines and the Medicare Local Coverage policies.

Claim Number: 18338812665000

Please refer to ICN 18310809384000 for the complete decision for this claim.

Claim Number: 19007808841000

Please refer to ICN 18310809384000 for the complete decision for this claim.

Who is Responsible for the Bill?

When services are denied as not medically reasonable and necessary under the Medicare program, we must also determine if the provider or beneficiary is liable for payment. Section 1879(a)-(g) of the SSA, also referred to as "the limitation on liability provision," specifies how to arrive at this decision. Medicare regulations, 42 CFR 424, require providers to be familiar with Medicare rules and regulations. In addition, 42 CFR 411.406 provides criteria for determining when a provider is responsible for payment for the services considered not reasonable and necessary. This regulation states that providers are presumed to have knowledge of published Medicare coverage rules and regulations, Centers for Medicare and Medicaid Services (CMS) Rulings, Medicare coverage policies in CGS Administrators bulletins or websites, and acceptable standards within the local community. We find that Novocure is liable for the denied charges. The record does not support that the beneficiary was notified in advance that Medicare would likely deny payment.

Other Important Information

If you appeal this decision, the Administrative Law Judge (ALJ) will not consider new evidence unless you show good cause for not presenting the evidence to the QIC. This requirement does not apply to beneficiaries, unless a provider or supplier represents the beneficiary.

For information on how to appeal this decision, refer to the page titled "Important Information About Your Appeal Rights." If you need more information or have any questions, please call 1-800-Medicare (1-800-633-4227) [TTY/TDD: 1-800-486-2048] or the phone number listed on page one.

You can receive copies of statutes, regulations, policies, and/or manual instructions we used to arrive at this decision. For instructions on how to do this, please see ‘Other Important Information’ on the page entitled “Important Information About Your Appeal Rights.” The request must be submitted in writing to this office.

**Medicare Appeal
Number:**

1-8486340738

Appeal Details

Beneficiary	D. Christenson		
Provider	Novocure Inc.		
Claim Number	Date of Service	Procedure	Medicare QIC Decision
18310809384000	11/03/18	E0766: Elec Stim Cancer Treatment	Unfavorable
18338812665000	12/03/18	E0766: Elec Stim Cancer Treatment	Unfavorable
19007808841000	01/03/19	E0766: Elec Stim Cancer Treatment	Unfavorable

THIS IS NOT A BILL – Keep this letter or a copy for your records.

Revision Date

01272017

IMPORTANT INFORMATION ABOUT YOUR APPEAL RIGHTS

Your Right to Appeal this Decision

If you do not agree with this decision, you may appeal the decision to an Administrative Law Judge (ALJ) at the Office of Medicare Hearings and Appeals (OMHA). The ALJ will review the decision to determine whether it is correct.

As of January 1, 2018, you must have \$160.00 in dispute to appeal to an ALJ. A claim can be combined ("aggregated") with others to reach this amount if: (1) the other claims have also been decided or dismissed by a QIC; (2) all of the claims are listed on your request for review; (3) your request for review is filed within 60 days of receipt of all of the QIC dismissals being appealed; and (4) you explain why you believe the claims involve similar or related services.

You can find more information about your right to an ALJ review of a QIC decision at www.hhs.gov/omha or by calling 1-855-556-8475. This is a toll free call.

How to Appeal

To exercise your right to appeal, you must file a written request for an ALJ review within **60 days** of receiving this letter. If your request for review is being filed late, you must explain why your request is being filed late. After you file an appeal, you may check your appeal's status via the OMHA website at www.hhs.gov/omha (click on Appeal Status Lookup).

When preparing your request for review, please use **Form OMHA-100**, available at:

www.hhs.gov/omha/forms/index.html

If you do not use the form, your request for review must include the following:

1. The Beneficiary's name, address, and Medicare health insurance claim number;
2. The name and address of the person appealing, if the person is not the beneficiary;
3. The representative's name and address, if any;
4. The Medicare appeal number listed on the front page of this Reconsideration notice;
5. The dates of service for the claims at issue;
6. The reasons why you disagree with the QIC's dismissal; and
7. A statement of any additional evidence to be submitted and the date it will be submitted.

You must send a copy of the request for ALJ review to the other parties who received a copy of this decision (for example, the beneficiary or provider/supplier). Please **do not** send a copy of your review request to the QIC that issued this decision or to the Medicare Administrative Contractor that issued the Redetermination.

Mail your review request to (tracked mail is suggested):

HHS OMHA Central Operations
200 Public Square, Suite 1260
Cleveland, OH 44114-2316

OMHA processes Medicare **Beneficiary** appeals on a priority basis. If you are a Beneficiary or you represent a Beneficiary, mail your review request to:

HHS OMHA Central Operations
Attn: Beneficiary Mail Stop
200 Public Square, Suite 1260
Cleveland, OH 44114-2316

If you are a Beneficiary or represent a Beneficiary, you can also call the OMHA Beneficiary help line at 1-844-419-3358 for assistance. This is a toll free call. For more information on the OMHA Beneficiary prioritization program, including limitations for Beneficiaries represented by a provider/supplier, or a shared representative, visit the OMHA website at www.hhs.gov/omha or call the Beneficiary help line.

Who May File an Appeal

You or someone you name to act for you (your **appointed representative**) may file an appeal. You can name a relative, friend, advocate, attorney, doctor, or someone else to act for you.

If you want someone to act for you, you and your appointed representative must sign and date a statement naming that person to act for you and send it with your request for review. Call 1-800-MEDICARE (1-800-633-4227) to learn more about how to name a representative.

Help With Your Appeal

You can have a friend or someone else help you with your appeal. If you have any questions about payment denials or appeals, you can also contact your State Health Insurance Assistance Program (SHIP). For information on contacting your local SHIP, call 1-800-MEDICARE (1-800-633-4227).

Other Important Information

If you want copies of statutes, regulations, and/or policies we used to arrive at this dismissal, please write to us and attach a copy of this letter, at:

C2C Innovative Solutions, Inc.

A Medicare Contractor
P.O. Box 44163
Jacksonville FL 32231-4163

If you have questions, please call us at the phone number provided on the front of this notice.

Other Resources To Help You

1-800-MEDICARE (1-800-633-4227),
TTY/TDD: 1-800-486-2048

If you need large print or assistance, call 1-800-633-4227

June 07, 2019

**D. CHRISTENSON
5754 CLEVEDON LN
OSHKOSH, WI 54904-9729**

Medicare Reconsideration Decision

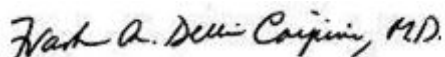
RE: Reconsideration Request
Reference attached chart for Appeal details

Dear D. Christenson:

Based on Medicare guidelines, you are entitled to a copy of our decision. Refer to the attached information for a description of the services that were at issue as well as our decision.

This notice is an informational copy for your records.

Sincerely,



Frank A. Delli Carpini, M.D.
Medical Director

Enclosure: Reconsideration decision

**Contact
Information**

If you have
questions, write or
call:

***C2C Innovative
Solutions, Inc.***

QIC DME
P.O. Box 44163
Jacksonville, FL
32231-4163

Telephone:
904-224-7433

Who we are:
We are a Qualified
Independent
Contractor (QIC).
Medicare has
contracted with us to
review your file and
make an independent
decision.

Summary of Facts

The service(s) shown below were submitted for payment to CGS Administrators. The explanation of the decision was released in a Medicare Summary Notice to the beneficiary and a Remittance Advice to the provider of service. A request for a Redetermination appeal was submitted to the Medicare Administrative Contractor (MAC). On March 11, 2019, CGS Administrators completed the appeal and sent notice of the decision to the appropriate parties. On April 22, 2019, we received a QIC Reconsideration request for the services referenced in the "Appeal Details" section. Information and records reviewed by the QIC in this case included:

- Refer to Explanation of Decision for Key Documents

Decision

A panel of clinical experts consisting of a physician and a licensed health care professional reviewed the claim(s).

The decision on your appeal is shown below:

Medicare Coverage	Claim Number (ICN)	Procedure /Date of Service
Non-covered	18310809384000	E0766: Elec Stim Cancer Treatment - (11/03/18)
Non-covered	18338812665000	E0766: Elec Stim Cancer Treatment - (12/03/18)
Non-covered	19007808841000	E0766: Elec Stim Cancer Treatment - (01/03/19)

We have determined that the provider is responsible for the denied charges.

Explanation of the Decision

Claim Number: 18310809384000

Claims for tumor treatment field therapy (TTFT) (E0766) for D. Christenson (Beneficiary or Appellant) were submitted by Novocure, Inc. (Novocure) for payment to CGS Administrators, LLC (CGS) the Durable Medical Equipment Medicare Administrative Contractor (DME MAC). The claims were denied with a finding that Medicare guidelines were not met.

On February 21, 2019, Novocure submitted a Redetermination Request to the DME MAC. On March 11, 2019, the DME MAC issued an unfavorable Redetermination Decision.

On April 22, 2019, C2C Innovative Solutions, Inc. (C2C), the DME Qualified Independent Contractor (QIC) received a Reconsideration Request dated April 16, 2019, from Debra M. Parrish, Esq. of Parrish Law Offices (also referred to as Appellant).

Key records contained in this case include:

DME MAC Redetermination Request dated February 21, 2019
DME MAC Redetermination Decision Letter dated March 11, 2019
Reconsideration Request dated April 16, 2019
Appointment of Representative (AOR) Form dated February 5, 2019
DME MAC Medical Directors Letter dated August 7, 2018
ALJ Decisions
National Comprehensive Cancer Network (NCCN) Guidelines
Centers for Medicare and Medicaid Services (CMS) Correspondence to Novocure
Clinical Studies
Food and Drug Administration Approvals
Invoice
Physician Order/Prescription
Physician Progress Notes
Diagnostic Results
Delivery Confirmation

Laws, Regulations, and Policy

For any item or service to be covered by Medicare, it must fall into a defined Medicare benefit category, it must not be statutorily excluded, it must be reasonable and necessary under § 1862(a)(1)(A) of the Social Security Act (SSA), and it must meet other Medicare program requirements for payment. Sections 414.200 through 414.232 of 42 the Code of Federal Regulations (CFR) cover payment for durable medical equipment and prosthetic and orthotic devices. The CMS Internet Only Manual (IOM), Medicare National Coverage Determinations (NCD) Manual, Publication (Pub.) 100-03, includes NCDs that pertain to certain Durable Medical Equipment, Prosthetics/Orthotics, and Supplies (DMEPOS) items. The Medicare Claims Processing Manual, Pub. 100-04, Chapter 20, instructs on billing and payment for DMEPOS. The Medicare Program Integrity Manual (PIM), Pub. 100-08, Chapter 5, provides guidance on medical review. The manuals are based upon the above cited law and regulations. DME MACs publish Local Coverage Determinations (LCDs) and related Policy Articles. The LCDs address the criteria for "reasonable and necessary," based on SSA § 1862(a)(1)(A). The articles encompass the non-medical necessity coverage and payment rules.

Reasonable and Medically Necessary

(a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—

(1)(A) which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, [SSA § 1862 (a)(1)(A)]

Authority of the QIC

Revision Date

01272017

With regard to authority of the QIC, 42 CFR § 405.968(b) provides:

(1) National coverage determinations (NCDs), CMS Rulings, and applicable laws and regulations are binding on the QIC.

(2) QICs are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but give substantial deference to these policies if they are applicable to a particular case. A QIC may decline to follow a policy, if the QIC determines, either at a party's request or at its own discretion, that the policy does not apply to the facts of the particular case.

(3) If a QIC declines to follow a policy in a particular case, the QIC's reconsideration explains the reasons why the policy was not followed.

(4) A QIC's decision to decline to follow a policy under this section applies only to the specific claim being reconsidered and does not have precedential effect.

(5) A QIC may raise and develop new issues that are relevant to the claims in a particular case provided that the contractor rendered a redetermination with respect to the claims. [42 CFR § 405.968(b)]

CMS Rulings

CMS Rulings are published under the authority of the Administrator of CMS. They are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS. [42 CFR §§ 401.108(c) and 405.1063(b)]

Definition – Contractor

Contractor means a carrier (including a Durable Medical Equipment Regional Carrier), or a fiscal intermediary (including a Regional Home Health Intermediary) that has jurisdiction for the LCD at issue. [42 CFR § 426.110]

LCD and NCD Reviews and Individual Claim Appeals

LCD and NCD reviews are distinct from the claims appeal processes set forth in part 405, subparts G and H; part 417, subpart Q; and part 422, subpart M of this chapter. [42 CFR § 426.310]

New LCD Request Requirements

Contractors [as defined in 42 CFR § 426.110] shall consider New LCD Requests to be a complete, formal request if the following are met:

- The request is in writing and can be sent to the MAC via e-mail, facsimile or written letter;
- The request clearly identifies the statutorily-defined Medicare benefit category to which the requestor believes the item or service falls under and provides a rationale justifying the assignment;

- The request shall identify the language that the requestor wants in an LCD;
- The request shall include a justification supported by peer-reviewed evidence. Full copies of published evidence to be considered shall be included and failure to include same invalidates the request;
- The request shall include information that addresses the relevance, usefulness, clinical health outcomes, or the medical benefits of the item or service; and
- The request shall include information that fully explains the design, purpose, and/or method, as appropriate, of using the item or service for which the request is made.

The MAC will review materials received within 60 calendar days upon receipt and determine whether the request is complete or incomplete. If the request is incomplete, the contractor shall respond, in writing, to the requestor explaining why the request was incomplete. If the request is complete, the MAC shall follow the process outlined in chapter 13 of Pub.100-08. A valid request response does not convey that a determination has been made whether or not the item or service will be covered or non-covered under 1862 (a)(1)(A) of the Act. The response to the requestor that the request is valid is simply an acknowledgement by the MAC of the receipt of a complete, valid request. [CMS IOM, Pub.100-08, PIM, Chapter 13, § 13.2.2.3]

LCD Reconsideration Process

The LCD reconsideration process is a mechanism by which a beneficiary or stakeholder (including a medical professional society or physician) in the MAC's jurisdiction can request a revision to an LCD. The LCD reconsideration process differs from an initial request for an LCD in that it is available only for final effective LCDs. The whole LCD or any provision of the LCD may be reconsidered. In addition, MACs have the discretion to revise or retire their LCDs at any time on their own initiative. [CMS IOM, Pub.100-08, PIM, Chapter 13, § 13.3]

Valid LCD Reconsideration Request Requirements

The requirements related to a valid LCD Reconsideration Request are as follows:

MACs shall consider all LCD reconsideration requests from:

- Beneficiaries residing or receiving care in a contractor's jurisdiction; and
- Providers doing business in a contractor's jurisdiction.
- Any interested party doing business in a contractor's jurisdiction.

MACs should only accept reconsideration requests for LCDs published as an effective final. Requests shall not be accepted for other documents including:

- National Coverage Determinations (NCDs);
- Coverage provisions in interpretive manuals;

- Proposed LCDs;
- Template LCDs, unless or until they are adopted and in effect by the contractor;
- Retired LCDs;
- Individual claim determinations
- Bulletins, articles, training materials; and
- Any instance in which no LCD exists, i.e., requests for development of an LCD.

If modification of the LCD would conflict with an NCD, the request would not be valid. The MAC should refer the requestor to the NCD reconsideration process. [CMS IOM, Pub.100-08, PIM, Chapter 13, § 13.3.2]

Reasonable and Necessary Provisions in LCDs

An item or service may be covered by a contractor LCD if:

- It is reasonable and necessary under 1862(a)(1)(A) of The Act. Only reasonable and necessary provisions are considered part of the LCD.

Reasonable and Necessary

Contractors [as defined in 42 CFR § 426.110] shall determine and describe in the LCD the circumstances under which the item or service is reasonable and necessary under 1862(a)(1)(A). Contractors shall determine if evidence exists to consider an item or service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:

Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;

Furnished in a setting appropriate to the patient's medical needs and condition;

Ordered and furnished by qualified personnel;

One that meets, but does not exceed, the patient's medical need; and

Revision Date

01272017

At least as beneficial as an existing and available medically appropriate alternative.
[CMS IOM, Pub.100-08, PIM, Chapter 13, § 13.5.4]

LCD L34823

LCD L34823 provides that TTFT will be denied as not reasonable and necessary. [LCD L34823 and Policy Article A52711]

Analysis

As noted above, this matter pertains to a denial of payment of claims for TTFT. Novocure disputed the denial and requested a Redetermination. The DME MAC issued an unfavorable Redetermination Decision. The DME MAC did not allow payment because the LCD states TTFT (E0766) is not reasonable and necessary. The Appellant has now requested a Reconsideration. At issue is payment for TTFT (E0766).

Please note the information obtained from the DME MAC, Novocure, and the Appellant was utilized in this Reconsideration Review. Documentation was evaluated to determine issues such as whether, in conjunction with other credible documentation, the service in question was actually provided or was provided as billed. The responsibilities of the QIC include rendering a decision only on the coverage or payment issues raised by the review request. The QIC may deny or reduce payment if it is believed the item or service at issue was not rendered or not rendered as billed. The QIC made a decision in this case based on whether the service was documented, appropriately ordered and delivered, and medically reasonable and necessary. The findings of this review are summarized below.

Appellant has set forth several arguments in the Reconsideration Request. Ms. Parrish, on behalf of the Beneficiary, opines that published literature supports the effectiveness of the device. In addition, she states the DME MAC Medical Directors have issued a statement indicating they do not interpret that the LCD applies to patients with newly diagnosed glioblastoma. Lastly, Ms. Parrish indicates the device is incorporated in the NCCN guidelines with a Category One designation.

The QIC has reviewed the correspondence Novocure received from CMS. The QIC finds the designation of an item as DME, is not an expression of coverage. In this instance, while the NovoTTFT-100A System has been classified as DME, the LCD is clear in that TTFT will be denied as not reasonable and necessary.

The QIC has also reviewed the letter from the DME MAC Medical Directors and LCD L34823. Appellant interprets the August 7, 2018, letter from the DME MAC Medical Directors to indicate that the LCD does not apply to newly diagnosed glioblastoma. Review of the LCD indicates that the LCD is silent on the type of glioblastoma and does not differentiate between the newly diagnosed and recurrent glioblastoma. The LCD states that TTFT will be denied as not reasonable and necessary. The letter from the DME Medical Directors does indicate that they accepted a Reconsideration Request to consider coverage of TTFT for newly diagnosed glioblastoma. The QIC has reviewed Chapter 13 of the PIM with respect to creation of new LCDs and the Reconsideration process for changes to an existing LCD. The PIM, in pertinent part, details the following:

The development process for the new LCDs is set forth in the Medicare PIM. The CMS IOM, Pub. 100-08, PIM, Chapter 13, § 13.3 also details the process for a beneficiary or stakeholder to request a revision to an LCD, which is called the LCD Reconsideration Process. This Reconsideration Process strictly relates to potential revisions to an LCD and is separate and apart from the claims appeal process as set forth in 42 CFR § 426.310. The CMS IOM, Pub. 100-08, PIM, Chapter 13, § 13.2.2.3 states that new LCD requests will be reviewed by the MAC within 60 days of receipt of all materials and determined whether the request is complete or incomplete. If the request is incomplete, the contractor shall respond, in writing, to the requestor explaining why the request was incomplete. If the request is complete, the MAC shall follow the process outlined in Chapter 13 of the PIM. A valid request response does not convey that a determination has been made whether the item or service will be covered or non-covered under SSA § 1862 (a)(1)(A). The response to the requestor that the request is valid is simply an acknowledgement by the MAC of the receipt of a complete, valid request.

The CMS IOM, Pub. 100-08, PIM, Chapter 13, § 13.3.2 details that MACs shall consider all LCD reconsideration requests from: Beneficiaries residing or receiving care in a contractor's jurisdiction; and Providers doing business in a contractor's jurisdiction; and Any interested party doing business in a contractor's jurisdiction. MACs should only accept Reconsideration Requests for finalized LCDs that are effective and published. Requests shall not be accepted for other documents including: NCDs; Coverage provisions in interpretive manuals; Proposed LCDs; Template LCDs, unless or until they are adopted and in effect by the contractor; Retired LCDs; Individual claim determination; Bulletins, articles, training materials; and Any instance in which no LCD exists, i.e., requests for development of an LCD. If modification of the LCD would conflict with an NCD, the request would not be valid. The MAC should refer the requestor to the NCD reconsideration process. Requests shall be submitted in writing and shall identify the language that the requestor wants added to or deleted from an LCD. Requests shall include a justification supported by new evidence, which may materially affect the LCD's content or basis. Copies of published evidence shall be included. Any request for LCD reconsideration that, after MAC review, is determined to not meet these criteria is invalid. The CMS IOM, Pub. 100-08, PIM, Chapter 13, § 13.5.4 provides that an item or service may be covered by a contractor LCD if: it is reasonable and necessary under § 1862(a)(1)(A) of the SSA. Only reasonable and necessary provisions are considered part of the LCD. Contractors, as defined in 42 CFR § 426.110, shall determine and describe in the LCD the circumstances under which the item or service is reasonable and necessary under § 1862(a)(1)(A). Contractors shall determine if evidence exist to consider an item or service to be reasonable and necessary if the contractor determines that the service is: Safe and effective; Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is: furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member; Furnished in a setting appropriate to the patient's medical needs and condition; Ordered and furnished by qualified personnel; One that meets, but does not exceed, the patient's medical need; and At least as beneficial as an existing and available medically appropriate alternative.

The CMS IOM, Pub. 100-08, PIM, Chapter 13, § 13.5.4 further details that Contractor LCDs shall be based on the strongest evidence available. The extent and quality of supporting evidence is key to defending challenges to LCDs. The initial action in gathering evidence to support LCDs shall always be a search of published scientific literature for any available evidence pertaining to the item or service in question. In order of preference, LCDs should be based on: Published authoritative evidence derived

from definitive randomized clinical trials or other definitive studies, and general acceptance by the medical community (standard of practice), as supported by sound medical evidence based on: scientific data or research studies published in peer-reviewed medical journals; Consensus of expert medical opinion (i.e., recognized authorities in the field); or Medical opinion derived from consultations with medical associations or other health care experts.

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

LCDs that challenge the standard of practice in a community and specify that an item or service is never reasonable and necessary shall be based on sufficient evidence to convincingly refute evidence presented in support of coverage.

The QIC understands that the DME MACs have found a request for reconsideration for newly diagnosed glioblastoma as valid. However, the DME MACs have not issued a new LCD providing coverage for newly diagnosed glioblastoma. The acceptance of a reconsideration request as valid by the DME MAC is not in and of itself evidence of the DME MAC's intent to allow coverage. It is merely an acknowledgement that the request for reconsideration was deemed valid, as set forth in the PIM.

According to the documentation submitted, the TTFT is being used to treat the Beneficiary's diagnosis of glioblastoma. The Appellant argues that the device is reasonable and necessary and published literature supports the effectiveness of the device. However, the QIC has reviewed the NCCN guidelines and the medical literature and finds the medical documentation of the efficacy of this device is not within the usual scope and breath of current medical literature with peer acknowledgment and review. More specifically, the QIC has reviewed the peer reviewed and evidence based literature relative to clinical trials for TTFT and found the literature and clinical trials to be limited in number and the clinical trials not non-biased; that is, the clinical trials were not independent, but funded by Novocure, Inc. The device is considered to be within the non-covered category for treatment of this condition as per the LCD.

The QIC has also reviewed LCD L34823, as noted above. The LCD for TTFT (L34823) states that for any item to be covered by Medicare, it must: 1) Be eligible for a defined Medicare benefit category; 2) Be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member; and 3) Meet all other applicable Medicare statutory and regulatory requirements. The purpose of an LCD is to provide information regarding reasonable and necessary criteria based on SSA § 1862(a)(1)(A) provisions. The LCD clearly and unequivocally states that TTFT (E0766) will be denied as not reasonable and necessary.

As noted above, the QIC understands that the DME MACs have found a request for reconsideration for newly diagnosed glioblastoma as valid. However, the DME MACs have not issued a new LCD providing coverage for newly diagnosed glioblastoma. The acceptance of a reconsideration request as valid by the DME MAC is not evidence of the DME MAC's intent to allow coverage. It is an acknowledgement that the request for reconsideration was deemed valid, as set forth in the PIM. The LCD L34823 details that TTFT (E0766) will be denied as not reasonable and necessary. This LCD

remains in effect until such time the DME MAC retires the non-coverage LCD or a new LCD becomes effective. Therefore, in accordance with the aforementioned LCD, the claim for TTFT services is determined to be not reasonable or necessary.

Based on the available documentation, the requirements of the LCD and PIM have not been met. Therefore, the claims cannot receive reimbursement.

Conclusion

The decision of the QIC is unfavorable. After careful consideration, the QIC finds that the services did not meet the requirements to be considered medically reasonable and necessary in the treatment of the patients, in tandem with the application of Medicare guidelines and the Medicare Local Coverage policies.

Claim Number: 18338812665000

Please refer to ICN 18310809384000 for the complete decision for this claim.

Claim Number: 19007808841000

Please refer to ICN 18310809384000 for the complete decision for this claim.

Who is Responsible for the Bill?

When services are denied as not medically reasonable and necessary under the Medicare program, we must also determine if the provider or beneficiary is liable for payment. Section 1879(a)-(g) of the SSA, also referred to as "the limitation on liability provision," specifies how to arrive at this decision. Medicare regulations, 42 CFR 424, require providers to be familiar with Medicare rules and regulations. In addition, 42 CFR 411.406 provides criteria for determining when a provider is responsible for payment for the services considered not reasonable and necessary. This regulation states that providers are presumed to have knowledge of published Medicare coverage rules and regulations, Centers for Medicare and Medicaid Services (CMS) Rulings, Medicare coverage policies in CGS Administrators bulletins or websites, and acceptable standards within the local community. We find that Novocure is liable for the denied charges. The record does not support that the beneficiary was notified in advance that Medicare would likely deny payment.

Other Important Information

If you appeal this decision, the Administrative Law Judge (ALJ) will not consider new evidence unless you show good cause for not presenting the evidence to the QIC. This requirement does not apply to beneficiaries, unless a provider or supplier represents the beneficiary.

For information on how to appeal this decision, refer to the page titled "Important Information About Your Appeal Rights." If you need more information or have any questions, please call 1-800-Medicare (1-800-633-4227) [TTY/TDD: 1-800-486-2048] or the phone number listed on page one.

You can receive copies of statutes, regulations, policies, and/or manual instructions we used to arrive at this decision. For instructions on how to do this, please see ‘Other Important Information’ on the page entitled “Important Information About Your Appeal Rights.” The request must be submitted in writing to this office.

**Medicare Appeal
Number:**

1-8486340738

Appeal Details

Beneficiary	D. Christenson		
Provider	Novocure Inc.		
Claim Number	Date of Service	Procedure	Medicare QIC Decision
18310809384000	11/03/18	E0766: Elec Stim Cancer Treatment	Unfavorable
18338812665000	12/03/18	E0766: Elec Stim Cancer Treatment	Unfavorable
19007808841000	01/03/19	E0766: Elec Stim Cancer Treatment	Unfavorable

THIS IS NOT A BILL – Keep this letter or a copy for your records.

Revision Date

01272017

IMPORTANT INFORMATION ABOUT YOUR APPEAL RIGHTS

Your Right to Appeal this Decision

If you do not agree with this decision, you may appeal the decision to an Administrative Law Judge (ALJ) at the Office of Medicare Hearings and Appeals (OMHA). The ALJ will review the decision to determine whether it is correct.

As of **January 1, 2018**, you must have **\$160.00 in dispute to appeal to an ALJ**. A claim can be combined ("aggregated") with others to reach this amount if: (1) the other claims have also been decided or dismissed by a QIC; (2) all of the claims are listed on your request for review; (3) your request for review is filed within 60 days of receipt of all of the QIC dismissals being appealed; and (4) you explain why you believe the claims involve similar or related services.

You can find more information about your right to an ALJ review of a QIC decision at www.hhs.gov/omha or by calling 1-855-556-8475. This is a toll free call.

How to Appeal

To exercise your right to appeal, you must file a written request for an ALJ review within **60 days** of receiving this letter. If your request for review is being filed late, you must explain why your request is being filed late. After you file an appeal, you may check your appeal's status via the OMHA website at www.hhs.gov/omha (click on Appeal Status Lookup).

When preparing your request for review, please use **Form OMHA-100**, available at:

www.hhs.gov/omha/forms/index.html

If you do not use the form, your request for review must include the following:

1. The Beneficiary's name, address, and Medicare health insurance claim number;
2. The name and address of the person appealing, if the person is not the beneficiary;
3. The representative's name and address, if any;
4. The Medicare appeal number listed on the front page of this Reconsideration notice;
5. The dates of service for the claims at issue;
6. The reasons why you disagree with the QIC's dismissal; and
7. A statement of any additional evidence to be submitted and the date it will be submitted.

You must send a copy of the request for ALJ review to the other parties who received a copy of this decision (for example, the beneficiary or provider/supplier). Please **do not** send a copy of your review request to the QIC that issued this decision or to the Medicare Administrative Contractor that issued the Redetermination.

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HHS OMHA Central Operations
200 Public Square, Suite 1260
Cleveland, OH 44114-2316

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Other Important Information

If you want copies of statutes, regulations, and/or policies we used to arrive at this dismissal, please write to us and attach a copy of this letter, at:

C2C Innovative Solutions, Inc.

A Medicare Contractor
P.O. Box 44163
Jacksonville FL 32231-4163

If you have questions, please call us at the phone number provided on the front of this notice.

Other Resources To Help You

1-800-MEDICARE (1-800-633-4227),
TTY/TDD: 1-800-486-2048

If you need large print or assistance, call 1-800-633-4227

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- Writing: Office for Civil Rights, U.S. Department of Health and Human Services, 200 Independence Avenue SW, Room 509F, HHH Building, Washington, D.C. 20201

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- Visitando hhs.gov/ocr/civilrights/complaints.
- Escribiendo a la: Oficina de Derechos Civiles del Departamento de Salud y Servicios Humanos 200 Independence Avenue, SW Room 509F, HHH Building Washington, D.C. 20201

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May 01, 2019

**PARRISH LAW OFFICES
788 WASHINGTON RD.
PITTSBURGH, PA 15228**

RE:

Beneficiary: D. Christenson
MED ID#: *****QP33
Appellant: David Christenson

Dear D. Parrish:

This letter is to inform you that we received your reconsideration request on April 22, 2019. Medicare hired C2C Innovative Solutions, Inc. to review your appeal and make a decision.

What we do

We will look at your file carefully to make a decision. We will review Medicare rules to decide your case. If the items or service was denied as not being medically necessary, then we will ask a clinical panel to review your file.

In most cases, we will issue a decision within 60 days of your request.

What you can do

We ask that you submit any additional information you wish to have considered in your appeal to our office within 14 days. Evidence that is not submitted prior to the issuance of the reconsideration decision will not be considered at the Administrative Law Judge (ALJ) level, or made part of the administrative record, unless the appellant demonstrates good cause as to why the evidence was not provided prior to the issuance of this decision. See 42 Code of Federal Regulations (CFR) §405.966(a)(2). This requirement does not apply to beneficiaries, unless they are represented by a physician, supplier or a provider of services. Submission of all evidence will allow us to thoroughly address the issues of the case and provide an

Contact Information

If you have questions, write or call:

***C2C Innovative
Solutions, Inc.***

QIC DME
P.O. Box 44163
Jacksonville, FL
32231-4163

Telephone:
904-224-7433

Who we are:
We are a Qualified
Independent
Contractor (QIC).
Medicare has
contracted with us to
review your file and
make an independent
decision.

accurate determination for your appeal. Due to a rapid increase in claim appeals at the third level of Medicare appeal, a substantial backlog has resulted that has increased the average time to decision. Our review of all pertinent supporting documentation and medical evidence will help to ensure that cases are resolved as early as possible in the appeals process.

When submitting additional documentation, please ensure the Medicare Appeals Number referenced in the upper right corner on this letter is included on all information you would like to submit and fax it to (904) 224-2760. You can also mail this information to:

QIC DME
P.O. Box 44163
Jacksonville, FL 32231-4163

You do not have to call or write to us to find out our decision. We will review your file and send you our decision.

How to get more information:

If you want a status update on your appeal, you can contact:

Beneficiaries: call 1-800-MEDICARE (1-800-633-4227)

Providers: check www.Q2A.com

For questions about your appeal other than status, please call 904-224-7433.

Sincerely,

Brian Stotler,
DME QIC-C2C Innovative Solutions, Inc.
Medicare Contractor

Medicare Appeal Number: 1-8486340738

Appeal Details

Appellant	David Christenson
AC	CGS Administrators(17013)

Redetermination Number	Provider	Date of Service
19053000193	N/A Novocure, Inc.	11/03/2018
19053000193	N/A Novocure, Inc.	12/03/2018
19053000193	N/A Novocure, Inc.	01/03/2019

THIS IS NOT A BILL – Keep this letter or a copy for your records.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF MEDICARE HEARING AND APPEALS
DEPARTMENTAL APPEALS BOARD
MEDICARE OPERATIONS DIVISION

In the Matter of:

DAVID CHRISTENSON,

Appellant,

v.

**CENTERS FOR MEDICARE & MEDICAID
SERVICES,**

Respondent.

Appeal No. **1-8630709341**

The above-entitled matter came on for hearing pursuant to notice before **SCOTT M. WATSON**, Administrative Law Judge, at the **Office of Medicare Hearings and Appeals, Cleveland, Ohio**, on **Wednesday, August 28, 2019**, at **11:00 a.m.**

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1378 Cape St. Claire Road
Annapolis, MD 21409
(410) 974-0947

A P P E A R A N C E S

On Behalf of the Appellant:

DEBRA PARRISH, Attorney
Parrish Law offices

On Behalf of the Respondent:

Free State Reporting, Inc.
1378 Cape St. Claire Road
Annapolis, MD 21409
(410) 974-0947

I N D E X

<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIRECT</u>	<u>RECROSS</u>
Timothy Parks	5	--	--	--

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E X H I B I T SEXHIBITSFOR IDENTIFICATIONIN EVIDENCE

Exhibits

3

3

(Time Noted: 11:04 a.m.)

JUDGE WATSON: All right then, we're now on the record.

My name is Scott Watson. I'm an administrative law judge with the Office of Medicare Hearings and Appeals in Cleveland, Ohio. Today's date is October -- excuse me -- August 28th, 2019. The time is now 11:04 a.m. Eastern Time, and this hearing is being conducted by telephone. I am making a digital recording of today's hearing and it will be made part of the record.

Today we're considering ALJ Appeal Number 1-8630709341. The Appellant's name is David Christenson, C-h-r-i-s-t-e-n-s-o-n. This appeal concerns the denial of Optune Tumor Treatment Field Therapy on November 3rd, December 3rd of 2018, and January 3rd of 2019.

Is that what you have, Ms. Parrish?

MS. PARRISH: It is.

JUDGE WATSON: All right. Would the participants introduce yourselves on the record, please? I'll start with you, Ms. Parrish.

MS. PARRISH: Yes. This is Debbie Parrish. I am counsel to the Medicare beneficiary in this matter, Mr. Christenson.

MR. PARKS: And hi, Your Honor. My name is Timothy Parks, P-a-r-k-s. I am a registered nurse with a BSN, a published research author pertaining to anti-cancer medicine, and the clinical appeal specialist here at Novocure, which supplies the

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1 device to the beneficiary.

2 JUDGE WATSON: All right, thank you.

3 It appears that the amount in controversy timely filing
4 requirements have been met. The qualified independent
5 contractor that issued the reconsideration decision was
6 provided a written notice of this hearing and elected not to
7 participate.

8 I believe that the issue for me to decide in this appeal
9 is whether, pursuant to the applicable Medicare law, David
10 Christenson, a Medicare beneficiary, satisfies the criteria for
11 coverage of Optune tumor treatment field therapy, under
12 Medicare Part B for the dates of service, November 3rd, 2018,
13 December 3rd, 2018 and January 3rd of 2019.

14 Do you agree, Ms. Parrish, that that's the issue before
15 me?

16 MS. PARRISH: It is, Your Honor.

17 JUDGE WATSON: This is a de novo hearing, which means I'll
18 be taking a fresh new look at the, this claim for coverage by
19 Medicare. I'm not bound by any prior determinations. I'll
20 issue a written decision after this hearing based on the
21 exhibits that are admitted into evidence and any testimony that
22 was provided at this hearing.

23 My office has prepared an exhibit list for this case, and
24 the list of exhibits reflects the documents that I have in the
25 record before me today.

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1 Did you receive a copy of the exhibit list, Ms. Parish?

2 MS. PARRISH: I did, Your Honor.

3 JUDGE WATSON: Any objection to my considering the
4 documents described in the exhibit list as I decide this
5 appeal?

6 MS. PARRISH: No objection, Your Honor.

7 JUDGE WATSON: Without objection, the documents described
8 in the exhibit list are admitted and are officially made a part
9 of the record.

10 **(Hearing exhibits marked for identification and received into**
11 **evidence.)**

12 **(Witness sworn.)**

13 JUDGE WATSON: All right. All right, go ahead,
14 Ms. Parish, and tell me what you want me to know about this
15 appeal.

16 MS. PARRISH: Okay. One, Your Honor, unfortunately, I
17 submitted the prehearing brief July 5th, and I think Your Honor
18 is aware that on the July 18th, 2019, the Medicare contractors
19 issued a final LCD, extending Medicare coverage to tumor
20 treatment field therapy. So I would propose submitting that to
21 you to the extent you don't want to take judicial notice of it,
22 I'm happy either way.

23 But significantly, the effect of that, however, is under
24 42 C.F.R. 426.420(b), when a contractor revises an LCD that has
25 been the subject of an LCD challenge, that has the same effect

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1 as a judicial ruling that the LCD wasn't valid. So, as we sit
2 here today, there is no valid LCD to apply against this
3 beneficiary's claim. In fact, unfortunately, had the
4 contractors completed the LCD reconsideration process last year
5 we might not be here today, but they did not.

6 So, with no consideration now for the LCD, I believe, I
7 have to share with you, I still get reconsideration decisions
8 that still repeat the same phrases despite this significant
9 legal development and, clearly, they keep saying there's no
10 evidence that the contractors intend to cover this, which
11 beggars the imagination in view of the significant events that
12 have occurred over the last 6 months, including Contract
13 Advisory Committee meeting, the draft LCD, finding that the LCD
14 record does not support the (indiscernible) of the LCD and now
15 the issuance of a final LCD explicitly extending coverage. So
16 unfortunately, the QIC's tune has not changed, despite
17 significant facts, that a wider assertion that there isn't
18 sufficient literature, it isn't sufficient studies, or that the
19 contractors have not indicated it.

20 Also, for Mr. Christenson, he has had multiple prior ALJ
21 decisions which again speak to the medical necessity based upon
22 his particular medical condition. He did -- actually he was
23 just diagnosed, and I'll have Mr. Parks speak to this more
24 specifically, he was diagnosed with a glioblastoma back in
25 2015. And it appears that there was an area of enhancement,

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1 and then he started using this treatment. Since that time he
2 has had stable MRIs.

3 But regardless of what -- whether he was considered newly
4 diagnosed or recurrent, I'll have Mr. Parks speak to that, he
5 clearly has benefited, because he continues to be with us here
6 today without evidence of disease progression over these dates
7 of service I have before you.

8 With that, I don't know if you have any questions for me.
9 I now ask that Mr. Parks specifically speak to this
10 beneficiary's clinical presentation.

11 MR. PARKS: Yes. Hi, Your Honor. As Ms. Parrish has
12 already explained, originally back in 2015, July 16th to be
13 exact, after a few weeks of headaches and vomiting, he went to
14 the hospital, and the MRI picked up a right occipital lobe
15 tumor. The tumor was then resected on July 17th of 2015. The
16 pathology confirmed that it was glioblastoma. As with the
17 standard of care, he completed a course of chemoradiation
18 therapy, which went from August 17th, 2015 through September
19 28th of 2015.

20 As Ms. Parrish also explained, on January 13th of 2016, an
21 MRI picked up an enhancement, or a recurrence. They then
22 treated that recurrence with a specific radiation therapy, like
23 radiation boost therapy, and that therapy was started on
24 January 21st of 2016. And that was followed by adjuvant
25 chemotherapy with temozolomide.

1 And then officially, on October 3rd of 2016, he was
2 started on Optune, and then they used Optune and temozolomide
3 together for 1 year, at which time he switched to Optune alone.
4 And as Ms. Parrish has stated, the MRIs that we have, have
5 shown that he remains stable. He is -- our compliance report
6 shows that he is using Optune 76 percent overall since he
7 started, and during these dates of service specifically, at 79
8 percent.

9 And then his KPS score is not necessarily listed as a KPS,
10 it's listed as an ECOG score, which is zero, which is
11 equivalent to a KPS score of 190, which means that while using
12 Optune, he is relatively -- actually, amazingly, he's pretty
13 mobile, self-sufficient. And he's benefitting from this
14 treatment. He is considered a recurrent patient at the time of
15 using Optune.

16 MS. PARRISH: Okay. Your Honor, do you have any further
17 questions about the beneficiary's clinical presentation?

18 JUDGE WATSON: Tell me the dates again. January 21st,
19 2016, that was -- what was that date?

20 MR. PARKS: Well they call it -- yeah. So January 21st of
21 2016 was the radiation boost treatment. It's like an
22 additional round of radiation after the chemoradiation, and
23 that was officially on January 21st of 2016.

24 JUDGE WATSON: Okay. Then Optune and temozolomide started
25 when?

1 MR. PARKS: So Optune started there -- or the temozolomide
2 was started after the radiation-like, so in February of 2016,
3 and then Optune wasn't started until October 3rd of 2016.

4 JUDGE WATSON: October 3rd, okay. And then, he went on
5 Optune only when?

6 MR. PARKS: So I would say in -- it doesn't specifically
7 say when they stopped it. They just say that they used it for
8 1 year, which would, for me, put it around February of 2017
9 that he stopped using the temozolomide. Usually that
10 chemoradiation, the doctor determines it's usually 6 months or
11 a year, depending on the benefit from the temozolomide.

12 JUDGE WATSON: I see.

13 MS. PARRISH: It's patient-specific, is my understanding.

14 JUDGE WATSON: Okay. So Ms. Parrish, in the past, in
15 other similar cases, you have characterized certain cases as
16 newly diagnosed, some as recurrent but where the individual
17 started TTFT while newly diagnosed and then there was a
18 recurrence. This one seems to be starting the Optune after a
19 recurrence; is that correct?

20 MS. PARRISH: That is correct, Your Honor. He -- this
21 person would be, I'd call a frank recurrent. So he did not
22 start the Optune device until after he had recurred, and it
23 appears, and I'm sure Mr. Parks -- the record, he had a
24 particularly aggressive tumor that grew back, unfortunately
25 quickly, before he was able to start other treatments.

1 JUDGE WATSON: And what's your legal argument as to the
2 status of the Medicare law for people who are recurrent before
3 they start Optune treatment?

4 MS. PARRISH: Sir, as we sit here right now, there is no
5 LCD that can be applied because the LCD itself, again, did not
6 distinguish between newly diagnosed or recurrent, has been
7 invalidated. With respect -- and I know Your Honor has seen
8 the future LCD which I often speak to, the future LCD includes
9 individuals who recurred, covers individuals who recurred after
10 they started as newly diagnosed.

11 A bit afield, but actually because the contractors elected
12 to cover some individuals who have recurrent glioblastoma but
13 not other individuals, such as Mr. Christenson, who did not
14 start the tumor treatment field therapy until after they
15 recurred, since then an LCD challenge has been filed with
16 respect to that restriction.

17 But my understanding of clinicians is, it can either work
18 for recurrent glioblastoma or it does not. You should not --
19 you just -- that's not a valid distinction, shall I say. Point
20 to, in this case, this beneficiary clearly has, looking at his
21 particular individual medical condition, clearly has benefited
22 because the life expectancy for a person that recurs is 6
23 months, Your Honor. He is still with us here today. You heard
24 Mr. Parks, he's stable MRI, which is remarkable, given his
25 tumor apparently was so aggressive that it grew back and before

1 he could initiate other treatment.

2 There's typically a window -- and Mr. Parks, please
3 correct me -- after you finish chemoradiation, typically a
4 window where they, before they start other types of treatments.
5 And it sounded like he recurred so quickly that he didn't get
6 that, to do anything else after that window.

7 From my perspective on this case, there is no valid LCD,
8 not specific to his individual condition, and the earlier
9 literature does support, and I think I've noted this before,
10 there is actually a separate article that looks at just
11 recurrent patients, that shows that those individuals clearly
12 benefit from not tumor treatment field therapy, but in terms of
13 overall survival and progression-free survival. That's a
14 (indiscernible) article.

15 JUDGE WATSON: Okay.

16 MS. PARRISH: And then my final point on that actually
17 would be there is no other treatment for people with recurrent
18 glioblastoma that's proved to be effective. They're kind of --
19 don't have other options, at this point.

20 JUDGE WATSON: I understand.

21 MS. PARRISH: Okay. All right. I have -- again, thank
22 you for your consideration, Your Honor, of this beneficiary.

23 JUDGE WATSON: All right. With that, I will consider
24 everything that's been presented today as well as the body of
25 evidence that's been taken into the administrative record.

1 I'll issue a written decision in the near future. And with
2 that, our hearing is adjourned.

3 MS. PARRISH: Thank Your Honor.

4 MS. PARRISH: All right, bye-bye.

5 MR. PARKS: Your Honor.

6 **(Whereupon, the hearing in the above-entitled matter was**
7 **adjourned.)**

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CERTIFICATION

This is to certify that the attached proceedings before the Office of Medicare Hearings and Appeals, in the matter of **DAVID CHRISTENSON v. CENTERS FOR MEDICARE AND MEDICAID SERVICES**, Appeal No. 1-8630709341, convened at Cleveland, Ohio on August 28, 2019, before Scott M. Watson, Administrative Law Judge, were held and recorded as herein appears, and that this is the original, complete, true and accurate transcript that has been compared to the reporting or recording accomplished at the hearing.



Pamela C. Jacobson
Transcriber

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